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14. ABSTRACT
We sought to test as part of 2 x 2 factorial design whether varying the numerical format of presenting breast cancer risk information using the Gail Score (percentage versus frequencies) and Tamoxifen's (percentage versus frequency)risks and benefits would affect among women eligible for Tamoxifen their perceptions of breast cancer risk, paying attention to and weighing of Tamoxifen's risks and benefits, interesting and using Tamoxifen, and their willingness to talk to their physician about Tamoxifen. Overall, there was no effect for formats across these outcomes. Overall, about half of the participants could not accurately state whether Tamoxifen's benefits exceeded the risks or vice versa. The majority (~70%) decided not take Tamoxifen; about 30% decided to delay making a decision. These data suggest that more research is needed to improve women's accuracy of weighing Tamoxifen's risk and benefits and exploring further why many decide not to take Tamoxifen, even among those who viewed they would personally benefit from its usage. Numerical display format played no role in these processes.

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tamoxifen, chemoprevention, breast, cancer, risk, communication

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I. Introduction (Per original submission)

The purpose of this study is to test how the numerical format of conveying breast cancer (BC) risk and the risks and benefits of taking Tamoxifen as a chemopreventive agent individually and jointly affect women's intentions to use Tamoxifen and talk to a health care provider about its use. The specific aims are to test how conveying (1) breast cancer risk as a frequency (e.g., 10 out of 10,000) or probability (e.g., .1%) affects perceived BC risks and negative emotions (e.g., fear, worry) about getting BC, the extent of processing information about Tamoxifen's risks and benefits (i.e., how much time is spent reviewing data on Tamoxifen), and intentions to use and talk to a health care provider about Tamoxifen use and (2) Tamoxifen's risks and benefits as frequencies or probabilities, individually and jointly interact with the BC risk format to affect women's weighing of the risks and benefits, intentions to use and talk with a health care provider about Tamoxifen use.

II. Background:

A.1. **Tamoxifen is a Promising Breast Cancer Chemoprevention Agent:** The FDA approved tamoxifen for reducing breast cancer (BC) risk in higher-risk women (i.e., defined as a five-year risk of invasive BC of 1.66% or greater), as a result of the BC Prevention Trial (BCPT, 1). Based on a sample of 13,388 women aged 35 and older with Gail scores (3) of $\geq$1.66%, the BCPT revealed that women who took 20 mg/day of tamoxifen had a 49% and 50% relative risk reduction of invasive and non-invasive BC, respectively, compared to women on placebo (1). The relative reduction in invasive BC was seen among women of all age groups. Trials in the United Kingdom and Italy did not find similar results. These discrepancies may be due to differences in sample sizes, number of BC cases, eligibility criteria and use of hormone replacement (4-5)**.** *Due to tamoxifen's shown efficacy as a BC chemoprevention drug in the BCPT, and its increased attention from the popular press and medical literature* (6-7)*, a significant number of women are expected to pursue or at least consider its use.*

A.2. **Decisions about the Personal Appropriateness of Tamoxifen Use are Complex:** Tamoxifen decisions are complicated by its array of benefits and risks in postmenopausal women. Tamoxifen reduces BC, fractures of the hip, wrist, and spine in postmenopausal women, but it elevates risks of endometrial cancer, pulmonary embolism, stroke, deep-vein thrombosis, and cataracts (1,7). *Given the competing risks and benefits, women, preferably in conjunction with their physicians, need help to make informed decisions about tamoxifen.*

A.3. **Decisions to Use Tamoxifen are Influenced by Perceived BC Risks:** A significant proportion of women at average and at higher risk for BC overestimate their chance of getting BC compared to their calculated probability (i.e., Gail score). However, they often believe they are at below or average risk, especially compared to other women (8-14). Based on theories of health behavior change (15-17), heightened perceived BC risk should motivate women to take precautionary or preventive measures (e.g., use tamoxifen). Indeed, our pilot results with average to higher risk women show that perceived BC risk and worry are related positively to interest in BC chemoprevention.

Ethics dictate that women being educated about chemoprevention be informed of their BC risk. Because most women overestimate their probability of getting BC, enhancing their risk accuracy usually entails lowering their perceived risk (12-14). The reduction in perceived risk, based on learning their Gail risk, can reduce interest in tamoxifen (see Appendix, Lipkus *et al*., under review). Because the 5-year probability of invasive BC rarely exceeds 7% (18), women may view their absolute statistical risks as very small. Risk education can have the unintended and potentially detrimental effect of reducing rather than enhancing the chance that women will consider tamoxifen. Such lack of consideration can have an adverse public health effect since among higher risk women, tamoxifen can confer substantial benefit (18).

A method that may counter a woman's tendency to diminish her BC risk, and yet result in improved accuracy, is to convey risk as a relative frequency (2 out of 100) rather than, as is current practice, in probabilities (e.g., 2%). Research by Slovic and colleagues and our preliminary work on tamoxifen decision-making shows that data on potential harmful events are seen as more risky when presented as

frequencies rather than probabilities (2, 19). It is the imagery causing qualities of frequencies and the resulting emotions these images elicit that may cause adverse events to be seen as more risky and positive events as more beneficial. In the proposed study, *women presented with their BC risk as a frequency should view their risk as higher and thus be more motivated to learn about tamoxifen than the women who receive BC risk feedback expressed as a probability.*

A.4. Well-tested Formats for Communicating Tamoxifen's Risks and Benefits are Lacking: Tamoxifen decisions are affected by its perceived risks and benefits. To inform women about these issues, Gail and colleagues (18) created algorithms that calculate a woman's likelihood of experiencing ten tamoxifen-related health events. The events are separated into three categories: 1) *life-threatening* (invasive BC, hip fractures, endometrial cancer, stroke, and pulmonary embolisms), 2) *severe* (noninvasive BC, deep-vein thrombosis), and 3) *other* (cataracts, spinal fractures, and colles' fractures). The algorithms specify the proportion of women expected to experience each health event with and without 5-year tamoxifen use, expressed in number per 10,000. As argued in section A.3., frequencies can make events seem more risky or prophylaxis more beneficial. Given the propensity to weigh negative information more heavily in decision-making (20-21), higher risk women are likely attend to and weigh more heavily tamoxifen's risks than benefits, especially when the risks are conveyed as frequencies rather than probabilities. Under what conditions will frequency information about tamoxifen's risks and benefits be viewed as most beneficial? This question has practical import, given that the frequency format is used by the drug manufacturer and recommended by experts on tamoxifen to communicate with the public. The proposed motivational information-processing model discussed below begins to address this critical question with respect to communicating the risks and benefits of tamoxifen.

A.5. Integrative Motivational Information Processing Model: We propose a model, based on motivated reasoning (22-25), that has five components: 1) formats for conveying BC risks, 2) effects of these formats on two mediating variables, risk perceptions and emotions, 3) effects of risk perceptions and emotions on information processing of tamoxifen's risks and benefits, 4) effects of formats for conveying tamoxifen's risks and benefits, and 5) interactions among these processes to affect the weighing of tamoxifen's risks and benefits, intentions to use tamoxifen and intentions to talk to a physician about its use.

The model predicts that conveying BC risk as a frequency rather than as a probability should increase perceived BC risk and negative feelings (e.g., worry, fear) about getting BC (components 1 and 2 above). Based on motivated reasoning, higher perceived risks and negative feelings should encourage women to seek information on how to reduce BC risk. As a result, they should attend more to tamoxifen's BC reducing benefits than to its risks (component 3), because focusing on these benefits is consistent with their motivation to reduce BC risk. Within this context, the benefits should appear more advantageous with frequencies than with probabilities. Hence, women who get BC risk feedback and tamoxifen's risks and benefits as frequencies should perceive its benefits to most strongly outweigh the risks; these stronger perceived benefits should lead to stronger intentions to use tamoxifen and talk to a physician about it (components 4 and 5).

Conversely, conveying BC risks as probabilities rather than frequencies should decrease perceived risk and negative feelings (e.g., worry, fear) about getting BC, resulting in less motivation to gather and process information about BC risk reduction (components 1 and 2) -- taking tamoxifen should be seen as less needed and hence as relevant. The reduced perceived need for tamoxifen, combined with our general tendency to weigh negative information such as risks more heavily than positive information such as benefits, should cause women to attend relatively more to tamoxifen's risks than benefits (component 3). Within this context, frequencies should make the risks appear more detrimental than probabilities. As a result, women who get BC risk feedback as probabilities and tamoxifen's risks and benefits as frequencies should perceive the risks as most strongly outweighing the benefits; these stronger perceived risks should lead to decreased intentions to use tamoxifen and talk to a physician about it. (components 4 and 5). *The*

proposed model merits testing as a guide for how medical experts may want to convey information about BC risks and tamoxifen, and chemopreventive drugs more generally.

III. Body: <u>Accomplishments as Outlined in the Approved Statement of Work</u>

A. Task 1: Prepare Experimental and Recruitment Materials

No work in this section was done in the last year. All tasks in this section were accomplished during prior years as summarized here: Development of all computer programs, preparation of risk communication formats and survey instruments, and pilot testing of recruitment methods, as outlined in the statement of work, were done in 2003/2004 and were reported in the 2004 progress report. Consent and the following questionnaires in order remain approved by the Duke University Medical Center Institutional Review Board (IRB): telephone screener, baseline, need for cognition, numeracy, BIS, EPrime (thoughts and feelings about breast cancer risk and tamoxifen), reaction to tamoxifen (percent and frequency versions), and 1 month follow up. Web based information for communicating information about cancer risks and tamoxifen risk and benefit also remains approved by the Duke University Medical Center Institutional Review Board (IRB). See Appendix D for copy of IRB approved study documents. All research staff were hired and trained in previous years.

B. Task 2: Conduct Recruitment and Experimental Procedures

During the period since the 2006 progress report, no significant changes were made to study design or instruments. No adverse events or study deviations occurred during this period. Final participants were seen in the laboratory in June 2007 and 1 month follow ups were completed in September 2007. We have applied for and were granted a no-cost extension until October 2007 to finish data collection and analysis.

Two deviations of protocol happened that were reported in the 2006 annual summary report; a third deviation was reported during the 2007 annual summary report as requested by the Duke IRB:

- In November 2004, it was noted that research staff were inadvertently pulling all appointments from the gynecology schedule, which included appointments scheduled by the doctors for procedures such as mammograms, bone scans, etc. These participants were not actually seeing their GYN provider. We corrected this problem and submitted a deviation notification to the Duke University Medical Center IRB on 11-19-2004 which was approved on 12-10-2004 (amendment activity number: 54301; see Appendix B) and since that time were longer getting participants unless they had a consultation scheduled with their provider. In the meantime, a few participants had entered the studies that had only a mammogram scheduled and were documented accordingly. No action was taken by the IRB as the problem was corrected by study staff who "should no longer be getting participants unless they have a consultation scheduled with their provider."
- In February 2005, it was noted that incorrect information was generated due to an internal error in the computer program that calculated risks for developing endometrial cancer, deep vein thrombosis, pulmonary embolism, cataracts, and stroke inaccurately. Rather than tailoring the risks based on age and race of the participant, all 21 participants were given the risks for a Caucasian female aged 35-39. Once the error was noted, a deviation notification was submitted to the Duke University Medical Center IRB on 2-11-2005 (amendment activity number: 71624; see Appendix B), along with an amendment to recontact these participants with correct risk information. This computer program was also corrected and all subsequent participants were given correct risk information for these five health states. IRB approved this on 3-9-2005 and no action was taken by them.

- In September 2006, we were monitored by the Duke University Medical Center Scientific Monitoring Subcommittee. The Scientific Monitoring Subcommittee issued a rating of Satisfactory (see Appendix C).
- In September 2007, we submitted the annual renewal submission to Duke IRB and were asked by them to submit a deviation to account for final enrollment of 308 when we were approved for enrollment of 300(amendment activity number: 104088; see Appendix B).

Our original planned enrollment was 400 women. We revised this target mid-study and were targeting recruitment for 250-300 women.

We mailed 5902 recruitment letters signed by 19 gynecologists and gynecology nurse practitioners affiliated with Duke University Medical Center. 2369 women did not complete the screening. Of those not completing the screening, 707 refused either via mail or on the telephone (most gave no reason for refusal or expressed lack of interest or time; 1 woman receiving the mailing worked on the study; 1 participant stated that she did not feel that the invitation for the study actually came from her physician); 444 went to their gynecology appointment and were no longer eligible to complete the screener; 1175 were left messages or were spoken to during a 3 month call window but were not reached or did not complete the screener; 42 had disconnected or wrong phone numbers; 1 was deceased.

3533 women completed the screening, which equates to a 60% response rate. Of those screened, there were 3051 ineligible (risk < 1.66%, prior diagnosis of breast cancer, DCIS, LCIS, prior clinical or research use of tamoxifen, or currently pregnant) and 482 women eligible for the study. Out of the 482 initially eligible women, 308 completed verbal consent and baseline survey (64%) beginning September 2004. Of the remaining 174, 142 withdrew prior to baseline for the following reasons (no interest, cannot travel, cannot make it to lab prior to gynecology appointment, cannot have any extra income, family or personal health problems, concerned about DOD funded research, prior prophylactic mastectomy); 27 were lost prior to baseline for the following reasons (already went to gynecology appointment, unable to recontact); 5 were deemed ineligible when screener information was confirmed for the following reason (risk <1.66% upon recalculation).

Among the 308 baseline surveys completed, 263 labs with written consent were completed; which equates to an 85% response rate among those who completed the baseline survey. With approval from the Duke University Medical Center IRB, we pilot tested the surveys and administered and evaluation form on the first 10 eligible participants and were satisfied, based on the results of the evaluation, with proceeding with the study. 45 participants who had completed baseline and consent did not complete the laboratory study with the following reasons: 25 participants (6%) withdrew (did not wish to proceed with the study for these reasons: too far to travel, too much hassle, cannot come prior to gynecology visit, no explanation, family health problems, no longer interested, car trouble, could not coordinate time with study staff, not feeling well); 17 (4%) were lost at the laboratory visit (met with their gynecologist and were thus no longer eligible to complete the lab, unable to recontact); 3 (.07%) were deemed ineligible at the beginning of the laboratory visit when screener information was verified and their risk was recalculated at <1.66% - they did not complete the lab.

Of the 263 participants completing the laboratory study, all were eligible to complete the one-month follow up. Of these, 251 (95%) have been completed. Of the remaining 12 who did not complete follow-up, 5 withdrew (no longer interested or no reason given) and 7 were lost (unable to recontact) prior to 1 month follow up.

C. Task 3: Conduct analyses of all data and submit main outcomes paper

We performed a literature search December 26, 2007 using Medline and Psychinfo from the years 2004

onward using the terms breast cancer, chemoprevention, attitudes, Tamoxifen, and communication. The relevant citations are provided at the end of this document (26-36). Overall, the findings have not changed significantly since the original citation. In general, there is some expressed interest in women taking Tamoxifen; however, the majority decide against its use due, in part, to treatment side effects. Further, discussion of Tamoxifen with primary care providers is less than optimal.

Publications with respect to our findings are forthcoming. Data collection for the study was not completed until September 2007, with analyses of the main findings ending middle of December. We will submit our findings for publications in 2008. Findings are summarized in the Key Research Accomplishments section of this report.

IV. Key Research Accomplishments

Our original hypotheses are as follows:

HI: Women who receive BC risk information as a frequency rather than as a probability (i.e., percentage) will view their risks as higher and will express more negative affect (e.g., worries, fear) about getting BC.

H2: Greater perceived BC risks and negative affect will lead to a stronger motivation to learn about tamoxifen and process information on tamoxifen's risks and (especially) benefits.

H3: The format used to convey BC risk will interact with the format used to convey tamoxifen's risk and benefits. Specifically, women who get BC risk feedback and data on tamoxifen's risks and benefits as frequencies will report: 1) the highest benefit and least risk for taking tamoxifen (i.e., highest benefit/risk ratio), and 2) the strongest intentions to use and talk to a physician (i.e., gynecologist) about tamoxifen.

Part A: Demographic Information - Overall, 263 patients completed all phases of this study. The demographic information for the entire sample and by each experimental condition is presented in Table 1.

Part B: Effects of Breast Cancer Risk Feedback on Perceived Breast Cancer Risk, Worry and Fear -Our first hypothesis was that women who receive breast cancer risk information (i.e., Gail score) as a frequency rather than as a probability (i.e., percentage) will view their risks as higher and will express more negative affect (e.g., worries, fear) about getting breast cancer. Table 2 presents the baseline and first follow-up values and the pre-post changes as a function of breast cancer presentational format (frequency or percentage). Contrary to predictions, format of conveying breast cancer risk did not result in any pre-post changes.

Part C: Information Seeking Patterns Involving the Computer Decision aid on Tamoxifen's Risks and Benefits: After receipt of their breast cancer risk score, participants reviewed on a computer Tamoxifen's risks and benefits – we developed an algorithm for determining risk and benefits per work by Gail and Colleagues (ref 18). Our computer-based decision aid gave women the option to select first the *category* of Tamoxifen' benefits or risks. Once selected, the program displayed the five health events associated with benefit or the five events associated with risk. The participant could then select any of these events. Once selected, the computer generated estimates of the actual risk or benefit numerically as a percentage or frequency out of 10,000 for that event. Participants could navigate throughout the program as they wished (e.g., going back to the main menu, selecting another benefit or risk, etc.). Below we present the main findings of patterns of correlates of information search**.**

C.1. What Information was Selected First? At the very start, participant could choose to look first at Tamoxifen's benefits or risks. In general, we expected that because of their higher risk status, participants would want to learn more about the benefits rather than the risks. Moreover, because it was hypothesized the frequency formats may make the risks easier to understand and/or imagine, we predicted that presenting breast cancer risk feedback as a frequency would be related to women choosing benefit information first more so than feedback presented as a percentage. In Table 3, we report what category was selected first and whether it varied by format of presenting breast cancer risk. As shown, participants were significantly more likely to choose the

category of benefits than risks firsts (p<.001). However, there was no effect for format of conveying breast cancer risk. Thus, the first hypothesis concerning information seeking was supported only.

C.2. Relationship between Perceptions of Risks, Worry and Fear and Selection of Tamoxifen's Risks and Benefits. We tested whether the decision to select first Tamoxifen's benefits or risks was related to perceptions of their breast cancer risks, worry and fear. We predicted that in general greater perceived breast cancer risks and negative affect (i.e., worry and fear) will lead women to process information more thoroughly on Tamoxifen's risks and especially benefits. In Table 4, we report the mean levels of each as these constructs as a function of whether they viewed the category of benefits or risks first – because we did not find an effect for format, we collapsed across this category. Contrary to our hypotheses, there were no differences in perceptions of risks – or objective risk – discriminating between participants who selected the benefits or risk category first; this pattern of result also applied to perceptions of lifetime worry and fear of getting breast cancer. However, participants who selected first benefit versus risk information reported higher five-year worry and fear. Thus, selection of benefit information seems to be driven more by shorter-term emotional responses to getting breast cancer, thus partially supporting our hypothesis.

C.3. Frequency and Time Spent Reviewing Tamoxifen's Benefits and Risks We examined how often and how much time participants reviewed each of the five benefits and risks – note that a participant could return and view an event more than once. We predicted that in general greater perceived breast cancer risks and negative affect (i.e., worry and fear) will lead women to spend more time reviewing information on Tamoxifen's risks and especially benefits. These results are reported in Table 5. In general, the vast majority viewed each event and typically only once. Of interest, although the total frequency for viewing the category benefits and risks was roughly equal, 1238 for benefits and 1266 for risks, more time was spent viewing the risks than benefits, 27,795 vs. 18,751 (56% vs. 44% respectively). We further broke down these results to explore how many minutes were spent reviewing each risk and benefits by presentation format. These results are presented in Table 7. Overall, results did not vary by format.

C.4. Relationship between Frequency reviewing Tamoxifen's Risks and Benefits and Formats of Presentation. The frequency counts reported in Table 5 were broken down by format of presenting breast cancer risk and Tamoxifen's risks and benefits. These results are presented in Table 7. There were no format main effects or interactions. On average, most events were viewed once. There was a trend (p<.051) such that benefits were viewed more often when the Tamoxifen format was a percentage rather than a frequency.

Part D. Outcomes related to Evaluating Tamoxifen's Risks and Benefits

D.1. Factual Knowledge of Tamoxifen's Risks and Benefits. We assessed how well participants understood the extent to which tamoxifen increased, decreased or did not affect the likelihood of occurrence for 10 health events; Tamoxifen was deemed associated with increased risk with five events and decreased risk with five events. We gave a score of 1, zero otherwise, if they correctly stated which health events were increased or decreased by taking Tamoxifen for five years. Scores ranged from 0 to 5 for benefits and risks. Below we report the results as a function of format of presenting breast cancer risk and Tamoxifen's risks and benefits (see Table 8). Overall, knowledge was relatively high across the formats. No significant main effects or interactions were found.

D.2. Weighing of Tamoxifen's Risk and Benefits. If participants indicated that Tamoxifen increased or decreased the likelihood of an event, we asked as a follow-up question to what extent the likelihood was increased or decreased using five point likert scales from slightly to a great deal. Scores ranged from -5 to 5 such that a positive value represented an increased risk, a negative value represented a decreased risk, and a score of zero meant the risk was unaffected by taking Tamoxifen. These findings are presented in Table 9 as a function of presentational formats of conveying breast cancer risks and Tamoxifen's risks and

benefits. Overall, there were no format main effects or interactions. As shown, in general, participants placed more weight of the risks occurring than the benefits.

D.3. Accuracy of weighing the risks and benefits of Tamoxifen. An important question is whether participants' overall perceived evaluation of Tamoxifen's risks and benefits matched that objective estimates. For example, if the objective estimates state the benefits outweigh the risks, do participates perceive it similarly? The objective weighing of Tamoxifen's risks and benefits of Tamoxifen was derived from computer generated algorithm. We examined to what extent patients' subjective evaluations of the risks and benefits coincided with the algorithm estimates, creating an index of when the risks outweighed the benefits and when the benefits outweighed the risks (n=262). The results are shown in Table 10. In 64% of the cases, the risks outweigh the benefits; in 34% of the cases the benefits outweighed the risks. Approximately 48% of the sample gave an estimate that was consistent with the algorithm estimates.

D.4. Effects of Presentational Format on Accuracy of Weighing Risks and Benefits We examined whether accuracy in weighing the risks and benefits differed as a function of the interaction between the format of presenting breast cancer risk and the format of presenting Tamoxifen's risks and benefits. These results are presented in Tables 11 through 13. Accuracy for when the risks outweighed the benefits, when the benefits outweighed the risks, and overall accuracy did not differ by presentation formats.

D.5. Effects of Perceived Risks, Worry and Fear on Accuracy of Weighing Risks and Benefits. It is possible that women who have higher short-term (five year) and lifetime perceptions of their risks, worry and fears will be more attentive to the estimates provided, leading to higher degrees of accuracy. We tested these predictions in logistic regression analyses predicting accuracy (1=accurate, 0 if not) from perceptions of risk, worry and fear (see Table 14). In general, as perceptions of five-year and lifetime risk, worry and fear increased, participants were less accurate in their perceptions of when the objective risks outweighed the benefits, but were more accurate in determining when the objective benefits outweighed the risks. Perceptions of risk, worry and fear were not associated with overall accuracy.

Part E. Outcomes involved in the decision to use Tamoxifen

E.1. Decisions Reached Concerning the use of Tamoxifen. As part of the one-month follow-up (N=251)**,** we asked women what decision they reached about taking Tamoxifen. As shown in Table 15, the vast majority (68%) decided not to take Tamoxifen, followed by delaying making any decision (24%). Only one participant decided to take Tamoxifen.

E.2. Discussion of use of Tamoxifen with Provider. Among the women who kept the gynecology appointment (N=226), we asked as part of the one-month follow-up whether they discussed the use of Tamoxifen with their provider. Overall, 57% (N=128) did have a discussion. We then tested whether discussions of Tamoxifen with the provider varied as a function of presentational format for conveying breast cancer risks and tamoxifen's risks and benefits. There results are presented in Table 16. Overall, 28 to 37 patients within each condition talked to their physician. However, there were no format main effects or interaction. Thus, our presentational formats did not affect discussions with the provider about Tamoxifen.

E.3. Associations between talking to a Provider about Tamoxifen and Perceptions of Breast Cancer Risks, Worry and Fear. We expected that participants who perceived themselves as greater breast cancer risk, and were more worried and fearful about getting breast cancer would be more likely to talk to their provider about Tamoxifen. In addition, we predicted that participants who perceived there to be a greater benefit to risk ratio of taking Tamoxifen would be more likely to talk to their provider than participants who perceived a greater risk to benefit ratio. We assessed how the above constructs assessed during the laboratory visit predicted talking to the provider about Tamoxifen at the one-month follow-up. These findings are presented in Table 17. Overall, perceptions of risk, worry and fear did not predict talking to a provider about

Tamoxifen – although may of the trends were in the right direction – with on exception. Participants who viewed their lifetime comparative breast cancer risk as greater than other women were more likely to talk to their provider about Tamoxifen. Further, patients perceived benefit to risk ratio and the actual ratio did not predict talking to the physician about Tamoxifen.

IV. Reportable Outcomes

No patents or licenses were obtained. No degrees were obtained by individuals supported by this award. No employment or research opportunities applied for based on experience/training supported by this award. A Microsoft Access database was created for the tracking and analysis of this study, but will not be used for any other purpose. A web-based interface was designed and used for the web-based section of the laboratory study, but will not be used for any other purpose.

We have cited this research in the preliminary studies section of a grant that was submitted to and received funding from the National Institutes of Health (NIH: Effects of Communicating Random Periareolar Fine Needle Aspiration Results on Decisions about Tamoxifen Use).

A poster was presented at the Era of Hope 2005 meeting-Department of Defense Breast Cancer Research Program Meeting in Philadelphia, PA. Interim analyses were performed for this and reported on the progress report for 2005. Final data collection for the study was not completed until September 2007 and has only been recently processed. We expect to submit our findings for publication in 2008.

V. Conclusions

Summary of findings:

Contrary to the extant literature that suggests frequency formats are preferred to other numerical formats, such as percentages, our study failed to find differences between formats for perceptions of risks, worry and fear, processing of information about Tamoxifen's risks and benefits, accuracy and knowledge concerning the risks and benefits, and decision reached and discussions about Tamoxifen. Rather, collapsing across formats we found several useful insights. First, short-term worry and fear were positively related to seeking information about Tamoxifen's risks and benefits. However, participants did review the benefit and risk information roughly equally. Second, 52% of the sample did not relate the objective estimates about personal risks and benefits to accurate perceptions of Tamoxifen's risk to benefit ratio. Therefore, significant more work is needed to identify how to convey this critical information. Third, almost all women decided not to take Tamoxifen or at least delay making the decision. Interestingly, even those who viewed there to be more benefits than risks and who perceived themselves as higher risk did not necessarily spend time talking to their providers about Tamoxifen. Clearly, what factors motivate these higher risk women to take Tamoxifen requires further research. Indeed, about a third of our participants may have benefited from Tamoxifen.

Our data suggest that more work is needed to help women accurately gauge the extent of the benefit and risks of Tamoxifen. For example, rather than present the risks and benefits for each health event, a summary score should be provided that then discusses what the score means. This presentation format can vary as a function of format as well as using visual displays. With respect to the latter, graphical formats can vary such factors as total benefit versus total risk, or present the residual risk and benefit. In addition, close to 60% of our patients discussed Tamoxifen with their provider. It cannot be established from this study how these communications ensued. Hence, future studies may involve the audio-taping of these discussions. Importantly, such studies may create interventions that can help physicians understand better the risks and benefits of taking Tamoxifen and how to communicate these findings to patients.

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VII. Supporting Data:

Table 1: Demographics.

			Breast cancer risk= frequency (F)		Breast cancer risk= percentage (P)	
		Full Sample	Tamoxifen risks=F	Tamoxifen risks=P	Tamoxifen risks=F	Tamoxifen risks=P
Age		54.64	54.73	55.14	53.74	54.96
Age at 1st child		27.89	28.57	28.19	26.46	28.42
Age at 1st period		12.55	12.28	13.22	12.31	12.43
Gail risk score		2.40	2.35	2.40	2.49	2.38
Race %	White	96.58	95.38	96.92	96.97	97.01
	Black	2.66	1.54	3.08	3.03	2.99
	Other	0.76	3.08	0	0	0
Education %	Some Highschool	0.76	0	0	3.03	0
	Highschool	7.6	6.15	7.69	13.64	2.99
	Trade/technical school	6.08	7.69	6.15	7.58	2.99
	Some college	19.01	18.46	26.15	18.18	13.43
	College	28.52	24.62	29.23	28.79	31.34
	Grad/post graduate	38.02	43.08	30.77	28.79	49.25
Mother with Breast cancer (%yes)		48.26	53.13	42.19	54.69	43.28
Sister with Breast cancer (%yes)		71.76	72.31	70.77	73.85	70.15
Daughter with Breast cancer (%yes)		1.32	0	3.03	2.17	0
Took hormone replacement %		24.05	20.31	30.77	25.76	19.4
Had a biopsy %		46.77	38.46	47.69	54.55	46.27
Number of Biopsies %	1	63.41	60	67.74	63.89	61.29
	2	24.39	20	25.81	19.44	32.26
	3	6.5	12	0	11.11	3.23
	4	2.44	0	0	5.56	3.23
	5	3.25	8	6.45	0	0
Uterus present (%yes)		75.19	74.63	80.0	69.70	76.47
Atypical hyperplasia (%yes)		4.1	4	3.23	5.56	3.33

Table 2: Means and standard deviations for perceptions of breast cancer risk, worry and fear.

Variable	Mean (SD) Baseline	Mean (SD) Laboratory	Breast Cancer Display Format*	
			Percentage (ns from 124-132)	Frequency (ns from 124-129)
Five year perceived BC risk (verbal)	3.11 (0.82)	2.99 (0.83)	-0.10 (.81)	-0.11 (.80)
Five year perceived BC Risk (numerical, percent)	33.92 (21.65)	14.95 (18.82)	-17.68 (21.60)	-19.84 (20.16)
Lifetime perceived BC risk (verbal)	3.74 (0.87)	3.61 (0.85)	-0.22 (.71)	-0.01 (.71)
Lifetime perceived BC risk (numerical)	48.00 (25.14)	28.94 (26.59)	-21.68 (24.38)	-16.04 (25.23)
Five year comparative risk	3.10 (0.86)	3.11 (0.89)	0.098 (0.83)	-0.078 (0.88)
Lifetime comparative risk	3.22 (0.86)	3.24 (0.83)	0.053 (0.67)	-0.023 (0.86)
Perceived 5-year worry	2.33 (0.93)	2.21 (0.79)	-0.09 (.83)	-0.13 (.77)
Perceived lifetime worry	2.72 (0.99)	2.62 (0.87)	-0.08 (.85)	-0.14 (.81)
Perceived five year fear	2.32 (1.00)	2.09 (0.88)	-0.24 (.89)	-0.19 (.89)
Perceived lifetime fear	2.59 (1.10)	2.49 (0.93)	-0.23 (.92)	-0.16 (.85)
Five year perceived BC risk (frequency, 100)	26.37 (18.59)	11.40 (15.30)	-15.43 (17.92)	-13.93 (20.22)
Lifetime perceived BC risk (frequency, out of 100)	37.99 (22.53)	21.23 (21.11)	-17.24 (20.87)	-15.90 (23.67)
Five year perceived BC risk (frequency, out of 10,000 women)	Not asked	433.81 (942.09)6	483.92 (1055.6)	382.53 (810.69)
Lifetime perceived BC risk (frequency, out of 10,000)	Not asked	984.37 (1623.5)	1039.96 (1588.3)	926.55 (1663.8)
Perceived risk based on Gail score feedback	NA	NA	3.11 (4.55)	235.23 (95.49)

* Difference score between baseline and laboratory. Higher values represent greater perceived risk, worry and fear. BC=breast cancer.

Table 3. What information was selected first in general and based on breast cancer presentation format.

Outcome	Percentage selected first	Breast Cancer Presentation Format		Statistical test and p-value
		Percentage	Frequency	
Risk viewed first	14.73	7.75	6.98	Chi-Square=0.0614 p-value=0.8042
Benefit viewed first	85.27	43.02	42.25	

Table 4. Means value of perceived breast cancer risks, worry and fear as a function of selecting Tamoxifen's benefits or risks first.

Variable	Selected a benefit first Mean (SD)	Selected a risk first Mean (SD)	t-test (risk-benefit) (p-value)
Breast cancer risk Gail score*	2.43 (0.97)	2.34 (0.69)	-0.59 (0.55)
Perceived five year risk verbal	3.02 (0.83)	2.84 (0.82)	-1.28 (0.20)
Perceived five year risk percentage	15.05 (18.47)	13.62 (20.85)	-0.43 (0.67)
Perceived five year risk frequency	11.33 (15.48)	10.58 (13.63)	-0.28 (0.78)
Perceived lifetime risk verbal	3.64 (0.82)	3.42 (1.010)	-1.51 (0.13)
Perceived lifetime risk percentage	29.31 (26.50)	25.38 (27.35)	-0.84 (0.40)
Perceived lifetime risk frequency	20.92 (20.93)	20.69 (21.16)	-0.06 (0.95)
Perceived lifetime risk frequency	918.63 (1504.74)	1250.92 (1952.32)	1.19 (0.23)
Perceived five year worry	2.26 (0.77)	1.89 (0.83)	-2.66 (0.008)*
Perceived five year fear	2.13 (0.87)	1.84 (0.95)	-1.67 (0.006)
Perceived lifetime worry	2.65 (0.86)	2.45 (0.92)	-1.33 (0.18)
Perceived lifetime fear	2.52 (0.92)	2.29 (1.01)	-1.42 (0.16)

* Converted to a percentage score.

Table 5: How often and how long participants viewed Tamoxifen's risks and benefits.

Health outcome of tamoxifen	Frequency	Total Seconds	Number of participants who viewed event
Hip fractures*	261	2362	233
Colles fractures of the wrist*	217	1924	209
Spine fractures*	238	3143	228
Invasive breast cancer*	270	5224	243
In-situ breast cancer*	280	7983	249
Cataracts+	239	2387	220
Stroke+	262	3614	241
Endometrial cancer+	249	4287	212
Pulmonary embolism+	250	3008	237
Deep vein thrombosis+	238	2083	226
Total for risks	1238 (50.56%)	27,795 (56%)	
Total for benefits	1266 (49.44%)	18,751 (44%)	

* benefit, + risk

Table 6: Mean total time spent reviewing Tamoxifen's risks and benefits as a function of presentational formats.

Health Event	Breast cancer risk =Percent		Breast cancer risk =Freq		One way ANOVA Chi-square with 3 df and p-value
	Percent (Tam)	Frequency (Tam)	Percent (Tam)t	Frequency (Tam)	
Hip fractures	9.03 (6.96)	9.13 (6.36)	9.86 (9.26)	7.52 (3.95)	3.35 (0.34)
Colles fractures of the wrist	8.89 (7.89)	8.96 (4.72)	8.97 (5.13)	8.15 (4.39)	0.65 (0.88)
Spine fractures	11.87 (8.19)	11.76 (7.72)	12.22 (7.66)	14.49 (26.95)	1.27 (0.74)
Invasive +++ breast cancer	16.59 (6.80)	23.59 (15.81)	19.00 (11.53)	19.29 (9.68)	11.64 (0.009)*
In-situ breast cancer*+++	26.75 (14.14)	34.02 (22.90)	26.26 (15.05)	28.93 (14.83)	8.14 (0.043)*
Cataracts+	10.65 (6.51)	10.95 (8.29)	10.06 (6.27)	8.98 (4.66)	2.61 (0.46)
Stroke+	13.45 (10.28)	15.32 (12.41)	11.63 (5.69)	15.07 (11.99)	4.81 (0.19)
Endometrial cancer+	17.27 (9.87)	19.17 (16.14)	16.32 (10.31)	16.65 (11.20)	1.75 (0.62)
Pulmonary embolism+	12.59 (17.34)	11.26 (9.42)	10.84 (6.13)	11.17 (8.70)	0.87 (0.83)
Deep vein thrombosis+	8.51 (5.42)	8.72 (6.09)	8.61 (5.41)	9.02 (6.58)	0.23 (0.97)
Total for benefits	68.88 (30.44)	80.63 (40.08)	74.20 (31.39)	69.89 (37.88)	4.50 (0.21)
Total for risks	56.63 (30.53)	56.01 (36.81)	53.64 (23.05)	53.74 (25.64)	0.53 (0.91)
Ratio of benefits to risk	1.56 (1.76)	2.259 (4.10)	1.53 (0.72)	1.56 (0.94)	4.44 (0.22)

Note: Outcomes are mean time in minutes (how often person looked at that event).

Table 7**:** Frequency of viewing Tamoxifen's risks and benefits as a function of presentational formats.

Health Event	Breast cancer risk =Percent		Breast cancer risk =Freq		Statistical test (ONE WAY ANOVA Chi-Square with 3 df) and (p-value)
	Percent (Tam)	Frequency (Tam)	Percent (Tam)	Frequency (Tam)	
Hip fractures*	1.14 (0.39)	1.15 (0.36)	1.08 (0.27)	1.11 (0.38)	1.43 (0.70)
Colles fractures of the wrist*	1.04 (0.22)	1.02 (0.14)	1.05 (0.23)	1.05 (0.21)	1.00 (0.80)
Spine fractures*	1.05 (0.22)	1.02 (0.13)	1.05 (0.22)	1.06 (0.24)	1.38 (0.71)
Invasive breast cancer	1.11 (0.41)	1.09 (0.34)	1.14 (0.35)	1.11 (0.30)	0.85 (0.84)
In-situ breast cancer*	1.13 (0.38)	1.13 (0.42)	1.16 (0.37)	1.08 (0.28)	1.26 (0.74)
Cataracts+	1.11 (0.31)	1.06 (0.23)	1.10 (0.31)	1.08 (0.27)	1.21 (0.75)
Stroke+ 101	1.08 (0.32)	1.09 (0.29)	1.10 (0.30)	1.08 (0.33)	0.17 (0.98)
Endometrial cancer+	1.26 (0.74)	1.14 (0.41)	1.14 (0.35)	1.15 (0.36)	2.29 (0.51)
Pulmonary embolism+	1.08 (0.28)	1.04 (0.18)	1.05 (0.22)	1.05 (0.22)	1.40 (0.71)
Deep vein thrombosis+	1.07 (0.25)	1.05 (0.23)	1.05 (0.23)	1.04 (0.19)	0.44 (0.93)
Total for benefits	5.08 (1.36)	4.86 (1.34)	5.27 (1.11)	4.93 (1.58)	7.78 (0.051)
Total for Risks	5.06 (1.61)	4.64 (1.46)	5.09 (1.31)	4.75 (1.47)	4.52 (0.21)
Ratio of benefits to risk	1.09 (0.59)	1.19 (0.81)	1.14 (0.66)	1.054 (0.44)	1.70 (0.64)

Note: Outcomes are mean frequencies (how often person looked at that event).

Table 8: Mean scores of knowledge as a function of BC and Tamoxifen formats (SD).

Knowledge score	BC format=percentage		BC format=Frquency	
	Tam format=perc.	Tam format=Freq	Tam format=perc	Tam format=Freq
Benefits (0-5)	4.44(1.19)	3.97 (1.68)	4.33 (1.29)	3.81 (1.67)
Risks (0-5)	4.11 (1.55)	4.14(1.35)	3.97 (1.75)	4.28 (1.12)
Total (0-10)	8.54 (2.25)	8.11 (2.57)	8.29 (2.57)	8.09 (2.43)

Table 9: Perceived weighing of risks and benefits as a function of BC and Tamoxifen formats.

Weighing scores	BC format=percentage		BC format=Frquency	
	Tam format=perc.	Tam format=Freq	Tam format=perc	Tam format=Freq
Benefits	-2.09 (1.27)	-2.05 (1.64)	-1.89 (10.9)	-1.95 (1.55)
Risks	2.08 (1.60)	2.64 (1.26)	1.79 (1.57)	2.69 (0.83)
Total	4.17 (2.09)	4.69 (2.32)	3.71 (2.10)	4.64 (1.93)

Table 10: Relationship between actual and perceived weighing of Tamoxifen's risks and benefits.

Objective weighing of risks and benefits	Participant Evaluation of Risks to Benefits		
	Risks outweigh benefits	Risks=benefits	Benefits outweigh risks
Risks outweigh benefits	93 (accurate)	39	35
Benefits outweigh risks	42	19	34 (Accurate)

Table 11: Accuracy of risks as a function of BC and Tamoxifen's formats of presentation.

Format of communicating breast cancer risks	Format of Communicating Tamoxifen's risks and benefits	
	Percentage	Frequency
Percentage	24	20
Frequency	18	31

Note: Outcome is percentage where the objective risks as estimated by the program match the evaluations given by the participant.

Table 12: Accuracy of benefits as a function of BC and Tamoxifen's formats of presentation.

Format of communicating breast cancer risks	Format of Communicating Tamoxifen's risks and benefits	
	Percentage	Frequency
Percentage	7	10
Frequency	8	9

Note: Outcome is percentage where the objective benefits are estimated by the program match the evaluations given by the participant.

Table 13: Accuracy of overall risks and benefits as a function of BC and Tamoxifen's formats of presentation.

Format of communicating breast cancer risks	Format of Communicating Tamoxifen's risks and benefits	
	Percentage	Frequency
Percentage	31	30
Frequency	26	40

Note: Outcome is percentage where the overall objective risks as estimated by the program match the evaluations given by the participant.

Table 14: Risk, worry, and Tamoxifen's risk benefit predicting accuracy scores.

Lab measure	Accuracy outcome		
	Risks outweigh benefits	Benefits outweigh risks	Overall Accuracy
Five year perceived BC risk (verbal)	0.775 (p=0.1091)	2.105 (p=0.0018)	1.093 (p=0.5526)
Five year perceived BC Risk (numerical)	0.982 (p=0.0208)	1.025 (p=0.0043)	0.998 (p=0.8034)
Lifetime perceived BC risk (verbal)	0.696 (p=0.0205)	2.353 (p=0.0005)	1.020 (p=0.8925)
Lifetime perceived BC risk (numerical)	0.988 (p=0.0187)	1.018 (p=0.0043)	0.999 (p=0.7653)
Five year comparative risk	0.701 (p=0.0151)	1.653 (p=0.0343)	0.880 (p=0.3615)
Lifetime comparative risk	0.670 (p=0.0113)	1.862 (p=0.0178)	0.883 (p=0.4066)
Perceived 5-year worry	0.586 (p=0.0022)	2.256 (p=0.0008)	0.903 (p=0.5156)
Perceived lifetime worry	0.635 (p=0.0037)	1.996 (p=0.0021)	0.903 (p=0.4761)
Perceived five year fear	0.599 (p=0.0014)	2.041 (p=0.0007)	0.903 (p=0.4701)
Perceived lifetime fear	0.691 (p=0.0112)	1.832 (p=0.0029)	0.947 (p=0.6852)

Note. Numbers represent odds ratios.

Table 15: Distribution of scores for what was decided to do about Tamoxifen.

Decision or Action taken	Distribution	
	Frequency	Percent
Not to take Tamoxifen	76	61.8%
Take Tamoxifen	1	0.81%
Delay making any decision	30	24.4%
Decided to get another opinion from another physician (e.g., referral)	9	7.3%
Other	7	5.7%

Table 16: Talking to Dr. about Tamoxifen as function of Breast Cancer and Tamoxifen format of presentation.

Format of communicating breast cancer risks	Format of Communicating Tamoxifen's risks and benefits	
	Percentage	Frequency
Percentage	37 (29%)	33 (25%)
Frequency	28 (22%)	30 (24%)

Note: Outcome is the number (percentage) who talked to their doctor about Tamoxifen.

Table 17: Risk, worry, and Tamoxifen's risk benefit ratio predicting talking to Dr. about Tamoxifen. (dependent variable: talking, yes=1, no=0)

Lab Measure	Odds ratio	(p-value)
Five year perceived Breast Cancer risk (verbal)	1.35	.07
Five year perceived Breast Cancer Risk (numerical)	1.01	.12
Lifetime perceived Breast Cancer risk (verbal)	1.37	.051
Lifetime perceived Breast Cancer risk (numerical)	1.00	.64
Five year comparative risk	1.31	.07
Lifetime comparative risk	1.65	.003
Perceived 5-year worry	1.27	.16
Perceived lifetime worry	1.16	.34
Perceived five year fear	1.30	.10
Perceived lifetime fear	1.27	.11
Perceived risk to benefit ratio	1.00	.22
Actual risk to benefit ratio	1.24	.20

VIII. Appendices

Appendix A: Biosketch for Lipkus, Isaac
Appendix B: IRB renewals/deviations (attached electronic file)
Appendix C: Scientific monitoring subcommittee report (attached electronic file)
Appendix D: Study documents(attached electronic files)
- D.1 cover letter for recruitment
- D.2 mailed screener
- D.3 telephone script and screener
- D.4 telephone baseline
- D.5 written consent
- D.6 Laboratory surveys
  - D.6.1 Need for cognition
  - D.6.2 Numeracy
  - D.6.3 BIS scale
  - D.6.4 Reaction to Breast Cancer Risk Feedback
  - D.6.5 EPrime program
  - D.6.6 Reaction to Tamoxifen Information (frequency and percentage versions)
- D.7 Tamoxifen One Month Follow up Questionnaire
- D.8 Protocol Summary

Appendix E: Key Personnel
Appendix F: Poster abstract from Era of Hope 2005 meeting-Department of Defense Breast Cancer Research Program Meeting in Philadelphia, PA

Appendix A

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Isaac M. Lipkus	Associate Professor
eRA COMMONS USER NAME Tigerbarb007	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
University of California, San Diego, CA	B.S.	1986	Sociology
University of North Carolina at Chapel Hill, NC	M.A.	1988	Social Psychology
University of North Carolina at Chapel Hill, NC	Ph.D.	1991	Social Psychology
Duke University Medical Center, Durham, NC	Post-Doc.	1991-1993	Behavioral Medicine
Ohio State University, Columbus, OH	Post-Doc.	1993-1994	Psychoneuroimmunology

A. Positions and Honors

1986 Cum Laude: University of California, San Diego
1992 Rubin Hill Award: Award for outstanding theoretical and empirical paper on interpersonal relations.
1994 New Directions Award: Award for outstanding theoretical and empirical paper that advances how researchers conceptualize and examine interpersonal processes.
1991-1993 Postdoctoral Fellow, Duke University Medical Center, Department of Psychiatry, Durham, NC
1992-1993 Correspondence Course Instructor, University of North Carolina at Chapel Hill, Department of Psychology, Chapel Hill, NC
1993-1994 Postdoctoral Fellow, Ohio State University, Department of Psychiatry, Columbus, OH
1994-1995 Visiting Assistant Professor, University of Wisconsin-Whitewater, Department of Psychiatry, Whitewater, WI
1994-1995 Adjunct Assistant Professor, Southwestern University, Department of Psychology, Kenner, LA
1995-1999 Assistant Research Professor, Duke University Medical Center, Department of Psychiatry, Program of Cancer Prevention, Detection and Control Research, Durham, NC.
2003-present Adjunct Associate Professor, University of North Carolina, School of Public Health, Health Education and Behavior Program, Chapel Hill, NC.
1999-2005 Associate Research Professor, Duke University Medical Center, Department of Psychiatry, Program of Cancer Prevention, Detection and Control Research, Durham, NC.
2005-present Associate Professor, Duke University Medical Center, Department of Psychiatry, Program of Cancer Prevention, Detection and Control Research, Durham, NC

B. Selected peer-reviewed publications (out of 77):

Rimer BK, Halabi S, Skinner Sugg C, Lipkus IM, Strigo TS, Kaplan EB, Samsa GP. Effects of a mammography decision-making intervention at 12 and 24 months. Am J Prev Med 22:247-257, 2002.

Stoddard AM, Fox SA, Costanza ME, Lane DS, Anderson MR, Urban N, Lipkus IM, Rimer BK. Effectiveness of telephone counseling for mammography: Results from five randomized trials. Prev Med 34:90-99, 2002.

Keller P, Lipkus IM, Rimer BK. Affect, framing, and persuasion. J. Marketing Res., 40:54-64, 2003.

Demark-Whenefried, W, Clipp EC, McBride CM, Lobach DF, Lipkus IM, Peterson, B, Snyder DC, Sloane R, Arbanas J, Kraus WE. Design of Fresh Start: A randomized trial of exercise and diet among cancer survivors. Med Sci Sports and Exerc. 35:415-424, 2003.

Keefe F, Lipkus IM, Lefebrve J, Hurwitz H, Clipp EC, Smith J, Porter J. The social context of gastrointestinal cancer pain: A preliminary study examining the relation of patient pain catastrophizing to patient perceptions of social support and caregiver stress and negative responses. Pain, 103:151-156, 2003.

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Lipkus IM, Green CG, Marcus A. Manipulating perceptions of colorectal cancer threat. Implications for screening intentions and behavior. J Health Comm., 8:213-228, 2003.

McBride CM, Emmons K, Lipkus IM. Understanding the potential of teachable moments: The case of smoking cessation. Health Educ Res, 18:156-170, 2003.

Rakowski W. Lipkus IM, Clark, MA, Rimer BK, Ehrich B, Lyna PR, Kornguth PJ. Comparing a reminder letter, tailored stepped-care and self-choice for repeat mammography. Am J Prev Med.. 25, 308-314, 2003.

Dement J, Pompeii L, Lipkus IM, Samsa GP. Cancer incidence among union carpenters in New Jersey. JOEM, 45, 1059-1067, 2003.

Lipkus IM, Samsa GP, Dement J, Skinner CS, Green LG, Pompeii L, Ransohoff DF. Accuracy of Self-reports of Fecal Occult Blood Tests and Test Results among Individuals in the Carpentry Trade. Prev Med., 37,513-519, 2003.

Lipkus IM, Skinner CS, Green LS, Dement J, Samsa GP, Ransohoff D. Modifying attributions of colorectal cancer risk. Cancer Epidemiol Biomarkers Prev., 13:560-566, 2004.

Lipkus IM, McBride CM, Lyna P, Pollack K. Interpretation of genetic susceptibility feedback among smokers with low socioeconomic status. Health Psych., 25, 308-314, 2004.

Lipkus IM, McBride CM, Pollak KI, Schwartz-Bloom RD, Tilson E, Bloom P. A Randomized Trial Comparing the Effects of Self-help Materials and Proactive Telephone Counseling on Teen Smoking Cessation. Health Psych., 23:397-406, 2004.

Synder DC., Sloane R., Lobach D., Lipkus IM, Clipp E, Krauss WE, Demark-Wahnefried W. Agreement between a brief mailed screener and an in-depth telephone survey: Observations from Fresh Start. JADA, 104:1593-1596, 2004.

Tilson EC, McBride CM, Lipkus IM, Catalano RF. Testing the interaction between parent-child relationship factors and
parent smoking to predict youth smoking. J Adol. health. 35:182-189, 2004.

Lipkus IM, Pollak KI, McBride CM, Schwartz-Bloom R, Lyna P, Bloom P. Assessing attitudinal ambivalence towards smoking and its associated with desire to quit among teen smokers. Psych Health, 20: 373-387, 2005.

Lipkus IM, Skinner CE, Dement J, Pompeii L, Moser B, Samsa G, Ransohoff D. Increasing colorectal cancer screening among individuals in the carpentry trade: Test of risk communication interventions. Prev Med, 40:489-501, 2005.

Lipkus IM, Klein W, Rimer BK, Skinner CS. Breast cancer risk perceptions and breast cancer worry: What predicts what? J Risk Res., 8:439-452, 2005.

Porter LS, Keefe FJ, Lipkus IM, & Hurwitz H. Ambivalence over emotional expression in patients with gastrointestinal cancer and their caregivers: Associations with patient pain and quality of life. Pain

Heimendinger J, O'Neill C, Marcus A, Wolfe P, Julesburg K, Morra M, Allen A, Davis S, Mowad L, Perocchia RS, Ward JD, Strecher V, Warnecke R, Novak M, Graf I, Fairclough, Bryant L, Lipkus IM. Multiple tailored messages are effective in increasing fruit and vegetable consumption among callers to the Cancer Information Service. J Health Comm, 10:65-82, 2005.

Marcus A, Mason M, Wolfe P, Rimer BK, Lipkus IM, Strecher V, Warneke R, Morra M, Allen AR, Davis SW, Gaier A, Graves C, Julesburg K, Nguyen L, Perocchia RS, Speyer JB, Wagner D, Thomsen C, Bright MA. The efficacy of tailored print materials in promoting colorectal cancer screening. Results from a randomized trial involving the National Cancer Institute's Cancer Information Service. J Health Comm, 10:83-104, 2005.

Bloom PN, McBride CM, Pollak K, Schwartz-Bloom R, & Lipkus IM. Recruiting teen smokers in shopping malls to a smoking cessation program using the Foot-in-the-Door Technique. JASP, in press.

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Lipkus IM, Klein WM. Effects of communicating social comparison information on risk perceptions for colorectal cancer. J Health Comm, 11:391-407, 2006.

Pollak KI, Oncken CO, Lipkus IM, Peterson BL, Swamy GK, Pletsch PK, Lyna P, Brouwer RJN, Fish L, Myers ER. Challenges and solutions for recruiting pregnant smokers into a nicotine replacement therapy trial. Nicot & Tob Res, 8:547-554, 2006.

Lipkus IM, Prokhorov AV. The effects of providing lung age and respiratory symptoms feedback on community college smokers' perceived smoking-related health risks, worries and desire to quit. Addict Beh., 32:516-32, 2007.

Goldenberg VK, Seewaldt VL, Scott V, Bean GR, Broadwater C, Fabian C. Kimler B, Zalles C, Lipkus IM. Atypia in Random Periareolar Fine Needle Aspiration Affects the Decision of High-Risk Women to Take Tamoxifen for Breast Cancer Chemoprevention. Can Epidemiol Biomarkers Prev., 16:1032-1034, 2007.

Lipkus IM. Numerical, Verbal and Visuals Formats of Conveying Health Risks: Suggested "Best Practices" and Future Recommendations. Med Decis Making, in press.

C. Research Support

Ongoing

NIH/NCI (Lipkus) 8/1/07-7/31/11
R01-CA121922
"Young Smokers' Reactions to Genetic Risk for Lung Cancer Susceptibility"
Purpose: This study explores how providing college smokers genetic feedback about their lung cancer susceptibility affects their risk perceptions for getting lung cancer and motivation to quit.

NIH/NCI (Lipkus) 9/11/07 – 8/30/09
R01 CA114389
"Increasing Attention to Smoking Risk Messages"
Purpose: to assess the relationship between smokers' perceptions of risk and motivations to seek out and process information about risks and cessation.

Foundation for Medical Decision-making (Lipkus, PI) 10/1/06-9/30-08
"Effects of Combining Decision Aids on Breast Cancer Adjuvant Treatment Expectations"
The purpose of this study is to determine whether providing breast cancer patients with a video about adjuvant treatments improves treatment expectations than usual care.

HHSN261200511005C (Lipkus, PI) 1/15/05 – 1/14/10
NIH/NCI
Cancer Information Service.
Purpose: To support the infrastructure, partnerships and research of the nationally recognized Cancer Information Service.

R01-CA105786 (Rimer/Lipkus, PI) 9/1/2003-8/31/08
NIH/NCI
"Finding the M.I.N.C for mammography maintenance"
The goal of this study is the use of a stepped care approach to maintain mammography adherence through the use of reminder systems, barriers counseling and having women think about the benefits of getting mammograms or the losses associated by not getting mammograms.
Role: Co-Investigator

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R21-CA120342 (Lipkus, PI) 04/23/07 –03/31/09
NIH/NCI
"Effects of Communicating RPFNA Results on Decisions about Tamoxifen Use"
The proposed study will be the first to address: 1) how patients factually understand and derive affective (i.e, emotional) meaning from the RPFNA result; 2) and how such understandings affect perceptions of BC risks and worry, and subsequent decision-making processes involving Tam; and 3) how numeracy and health literacy affect understanding, and as a result, perceptions of BC risk, and decision-making processes involving Tamoxifen. (Awaiting award letter, received priority score of < 2%).

R03 DK075842 (Lipkus, Co-Investigator) 7/15/06-6/30/08
NIH
"Risk Perception in Barrett's Esophagus"
The goal of this study is to assess the perception of cancer risk among subjects with Barrett's esophagus, and to determine whether subjects' perceptions of risk correlate with their healthcare utilization

R01-CA80953 (Myers, PI) 5/1/02-4/30/08
NIH/NCI
"Testing Pharmacological Therapies for Pregnant Smokers"

This is a two-arm design project. Aim one is Tailored Cognitive Behavioral Treatment (TCBT) that provides women with customized risk information about smoking and nicotine, the potential harms to the fetus and encouragement of appropriate behavioral skills building. Aim two is TCBT + NRT – the tailored intervention incorporating NRT information plus choice of patch or gum.

R03-CA132562
NIH/NCI (Johnson, PI) 12/01/07 - 11/30/09
"Strategies to help inform colorectal cancer risk magnitudes"
Purpose: This study will develop a comprehensive approach to discussing colorectal cancer risk, with an emphasis on more effective ways of communicating probabilistic information about getting colorectal cancer to motivate screening among individuals who have never screened for the disease.

Completed During the Last Three Years
DAMD17-03-1-03820 (Lipkus, PI) 5/1/03-9/30/07
DOD
The Effects of Information Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention
The purpose of this study is to examine how providing individualized risk estimates of breast cancer and the risk and benefits of tamoxifen for breast cancer chemoprevention, individually and jointly affect the decision to take tamoxifen among higher risk women.

W81XWH-05-1-0383 (Lipkus, Co-Investigator) 4/15/05 – 6/30/07
DOD
"Guilford County Genomic Medicine Initiative: Developing Models for Medical Practice"
The purpose of this grant is to explore how to use family history to promote prevention behaviors, cancer screening, and if needed, genetic testing. Among other things, this includes applying broad-based educational programs to the community and health care professionals,

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and utilizing a clinical approach that addresses the numerous technical, logistical, and operational challenges of such an endeavor.

CA89122 (Lipkus, PI) 9/13/02-9/12/06
NIH/NCI
Message Framing Effects on Youth's Smoking Behavior
This study explores the extent to which messages framed as gains or losses interact with community college smokers' stage of change to affect desire and intentions to quit smoking.

CA90716 (Lipkus, PI) 3/1/03-2/28/05
NIH/NCI
Affecting Perceived Risks and Ambivalence About Smoking
This study explores how manipulating perceptions of smoking-related risks and attitudinal ambivalence towards smoking independently and jointly affect college smokers' intentions to quit. This grant is under a no-cost extension.

R01-CA63782-03 (Lipkus, PI) 7/1/99-11/30/05
NIH/NCI
Increasing Colorectal Cancer Screening Among Carpenters
The main goals of this project are to assess whether 1) informing carpenters ages 50 and older about occupational and behavioral risk factors related to CRC, in addition to genetic risk factors, process incremental increases in CRC screening as compared to providing them with generic risk information only; and 2) the use of targeted telephone counseling, as a motivational adjunct, produces incremental increases in CRC screening as compared to written educational materials. This is under a no-cost extension.

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Appendix B

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DUKE UNIVERSITY HEALTH SYSTEM
Institutional Review Board for Clinical Investigations

NOTIFICATION OF APPROVAL

PI's Name: Isaac Marcelo Lipkus Registry Number: 3109-07-10R6ER

Title: The Effects of Information Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention

Sponsor: Department of Defense

IND#: IDE#: CMS Category:

The Duke University Health System Institutional Review Board for Clinical Investigations ("DUHS IRB") has conducted the following activity on the study cited above:

Activity: ○ Initial Review ◉ Continuing Review ○ Amendment Review /Amendment Review Date

Type of Review: ○ Full Board ◉ Expedited

Risk/Benefit Category (Studies with Pediatric Subjects):

Expiration Date: 10/15/2008 Review Date: 10/3/2007

Date of Declared Concordance with federally funded grant, if applicable:

Grant Number:

DUHS IRB approval encompasses the following specific components of the study cited above:

Protocol version/date	
Consent form version/date	N/A (enrollment ended)
Investigator Brochure version/date	
Summary version/date	7/8/2005
Amendment version/date	
Amendment Activity Number	
Other	

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

No change to the protocol, consent form or other approved document may be implemented without first obtaining IRB approval of the change. Any proposed change must be submitted as an amendment. If necessary in a life-threating situation, where time does not permit your prior consultation with the IRB, you may act contrary to the protocol if the action is in the best interest of the subject. You must notify the IRB of your action within five working days of the event

This study expires at 12 AM on the Expiration Date. At that time, all study activity must cease. If you wish to continue specific study activities directly related to subject safety, you must immediately contact Dr. John Falletta or Jody Power. This study must be submitted to the DUHS IRB for continuing review by the first day of the month preceding the month your protocol expires.

The DUHS IRB, FWA00009025, is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, and 45CFR164.508-514. In addition, except where in conflict with 21CFR56, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization. Additional policies and procedures of the DUHS IRB can be found at: http://irb.mc.duke.edu.

DUHS IRB Authorized Signature

JOHN M. FALLETTA, M.D.
IRB CHAIRMAN
DUKE UNIVERSITY HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD

10/5/07

(For new studies, subject accrual may begin.)

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DUKE UNIVERSITY HEALTH SYSTEM
Institutional Review Board for Clinical Investigations

NOTIFICATION OF APPROVAL

PI's Name: Isaac Marcelo Lipkus Registry Number: 3109-06-10R5ER

Title: The Effects of Information Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention

Sponsor: Department of Defense

IND#: IDE#: CMS Category:

The Duke University Health System Institutional Review Board for Clinical Investigations ("DUHS IRB") has conducted the following activity on the study cited above:

Activity: ○ Initial Review ◉ Continuing Review ○ Amendment Review /Amendment Review Date

Type of Review: ○ Full Board ◉ Expedited

Risk/Benefit Category (Studies with Pediatric Subjects):

Expiration Date: 10/15/2007 Review Date: 10/10/2006

Date of Declared Concordance with federally funded grant, if applicable:

Grant Number

DUHS IRB approval encompasses the following specific components of the study cited above:

Protocol version/date
Consent form version/date 10/13/2006
Investigator Brochure version/date
Advertisement version/date
Amendment version/date
Amendment Activity Number
Other

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

This study must be submitted to the DUHS IRB for continuing review by the first day of the month preceding the month your protocol expires.(Note: Expiration date is dependent upon Review Date, not final IRB approval date).

The DUHS IRB, FWA00009025, is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, and 45CFR164.508-514. In addition, except where in conflict with 21CFR56, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization. Additional policies and procedures of the DUHS IRB can be found at: http://irb.mc.duke.edu.

DUHS IRB Authorized Signature

JUDY F. POWER, M.S., M.B.A.
EXECUTIVE DIRECTOR
DUKE UNIVERSITY HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD

10/16/2006
Final IRB Approval Date
(For new studies, subject accrual may begin.)

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DUKE UNIVERSITY HEALTH SYSTEM
Institutional Review Board for Clinical Investigations

NOTIFICATION OF APPROVAL

PI's Name: Isaac Marcelo Lipkus Registry Number: 3109-05-10R4ER

Title: The Effects of Information Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention

Sponsor: Department of Defense

IND#: IDE#: CMS Category:

The Duke University Health System Institutional Review Board for Clinical Investigations ("DUHS IRB") has conducted the following activity on the study cited above:

Activity: ○ Initial Review ◉ Continuing Review ○ Amendment Review /Amendment Review Date

Type of Review: ○ Full Board ◉ Expedited

Risk/Benefit Category (Studies with Pediatric Subjects):

Expiration Date: 10/15/2006 Review Date: 10/13/2005

Date of Declared Concordance with federally funded grant, if applicable:

DUHS IRB approval encompasses the following specific components of the study cited above:

Protocol version/date	
Consent form version/date	10/13/2005
Investigator Brochure version/date	
Advertisement version/date	
Amendment version/date	
Amendment Activity Number	
Other	

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

This study must be submitted to the DUHS IRB for continuing review by the first day of the month preceding the month your protocol expires.(Note: Expiration date is dependent upon Review Date, not final IRB approval date).

The DUHS IRB, FWA00009025, is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, and 45CFR164.508-514. In addition, except where in conflict with 21CFR56, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization. Additional policies and procedures of the DUHS IRB can be found at: http://irb.mc.duke.edu.

DUHS IRB Authorized Signature

10/14/2005
Final IRB Approval Date
(For new studies, subject accrual may begin.)

JOSEPH C. FARMER, M.D.
CHAIRMAN
DUKE UNIVERSITY HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD

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DUKE UNIVERSITY HEALTH SYSTEM
Institutional Review Board for Clinical Investigations

NOTIFICATION OF APPROVAL

PI's Name: Isaac Marcelo Lipkus Registry Number: 3109-04-10R3ER

Title: The Effects of Information Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention

Sponsor: Department of Defense

IND#: IDE#: CMS Category:

The Duke University Health System Institutional Review Board for Clinical Investigations ("DUHS IRB") has conducted the following activity on the study cited above:

Activity. ○ Initial Review ◉ Continuing Review ○ Amendment Review /Amendment Review Date

Type of Review: ○ Full Board ◉ Expedited

Expiration Date: 10/15/2005 Review Date: 10/15/2004

Date of Declared Concordance with federally funded grant, if applicable:

DUHS IRB approval encompasses the following specific components of the study cited above:

Protocol version/date
Consent form version/date 10/18/2004
Investigator Brochure version/date
Advertisement version/date
Amendment version/date
Amendment Activity Number
Other

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

This study must be submitted to the DUHS IRB for continuing review by the first day of the month preceding the month your protocol expires.
(Note: Expiration date is dependent upon Review Date, not final IRB approval date).

The DUHS IRB, MPA #1106, is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, and 45CFR164.508-514. In addition, except where in conflict with 21CFR56, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization. Additional policies and procedures of the DUHS IRB can be found at: http://irb.mc.duke.edu.

DUHS IRB Authorized Signature

JOSEPH C. FARMER, M.D.
CHAIRMAN
DUKE UNIVERSITY HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARDS

10/18/2004
First IRB Approval Date
(For new studies, subject accrual may begin.)

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DUKE UNIVERSITY HEALTH SYSTEM
Institutional Review Board for Clinical Investigations

NOTIFICATION OF APPROVAL

PI's Name: Isaac Marcelo Lipkus Registry Number: 3109-03-10R2ER

Title: The Effects of Informational Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention

Sponsor: Department of Defense (pending)

IND#: IDE#: CMS Category:

The Duke University Health System Institutional Review Board for Clinical Investigations ("DUHS IRB") has conducted the following activity on the study cited above:

Activity: ○ Initial Review ◉ Continuing Review ○ Amendment Review /Amendment Review Date

Type of Review: ○ Full Board ◉ Expedited

Expiration Date: 10/2/2004 Review Date: 10/2/2003

Date of Declared Concordance with federally funded grant, if applicable:

DUHS IRB approval encompasses the following specific components of the study cited above:

Protocol version/date
Consent form version/date 10/7/2003
Investigator Brochure version/date
Advertisement version/date
Amendment version/date
Amendment Activity Number
Other

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

This study must be submitted to the DUHS IRB for continuing review by the first day of the month preceding the month your protocol expires.
(Note: Expiration date is dependent upon Review Date, not final IRB approval date).

The DUHS IRB, MPA #1106, is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, and 45CFR164.508-514. In addition, except where in conflict with 21CFR56, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization. Additional policies and procedures of the DUHS IRB can be found at: http://irb.mc.duke.edu.

DUHS IRB Authorized Signature

10/22/2003
Final IRB Approval Date
(For new studies, subject accrual may begin.)

JOHN M. HARRELSON, M.D.
VICE-CHAIR
DUKE UNIVERSITY HEALTH SYSTEM
INSTITUTIONAL REVIEW BOARD

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DUKE UNIVERSITY MEDICAL CENTER
Institutional Review Board for Clinical Investigations

IRB Approval

Multiple Project Assurance #1106
Institutional Review Board #

Principal Investigator: Isaac Marcelo Lipkus
Study Title: The Effects of Informational Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention
Sponsor: Department of Defense (pending)
IRB Registry #: 3109-02-9R1ER
Genetic Testing: ☐
IND Number IDE Number: Category A ☐ or B ☐
Grant Concordance Declared for NIH Studies on

TYPE OF REVIEW

☐ Full Board Meeting on ☑ Expedited Review on 9/6/2002

REASON FOR REVIEW

☐ Preliminary/Pilot Review
☑ Renewal Review
☐ New Study Implementation Review
☐ Amended Protocol Review on #

IMPORTANT REMINDERS

PROBLEMS OR ADVERSE REACTIONS:
If any problems in the treatment of human subjects or unexpected adverse reactions occur which may be related to this study, you MUST notify an IRB Chairman IMMEDIATELY.

CHANGES IN PROTOCOL:
If there are changes in procedures or changes in the study protocol, you MUST notify the IRB Chairman BEFORE they are implemented unless the changes are for enhancing subject

RENEWAL:
You are required to apply for renewal of approval at least annually for as long as the study is active. Your next review date should be on or before 9/10/2003.

IRB Authorization Signature — GEORGE R. PARKERSON, JR., MD, MPH, CHAIRMAN #3, INSTITUTIONAL REVIEW BOARD

9/25/02
Signature Date

cc: Principal Investigator
IRB Administrator

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DUKE UNIVERSITY MEDICAL CENTER
Institutional Review Board for Clinical Investigations

IRB Approval

Multiple Project Assurance #1106
Institutional Review Board # 1

Principal Investigator: Isaac Marcelo Lipkus
Study Title: The Effects of Informational Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention
Sponsor: Department of Defense
IRB Registry #: 3109-01-9R0ER
Genetic Testing: ☐
IND Number: IDE Number: Category A ☐ or B ☐
Grant Concordance Declared for NIH Studies on 9/13/2001

TYPE OF REVIEW

☐ Full Board Meeting on 9/10/2001 ☑ Expedited Review on 9/10/2001

REASON FOR REVIEW

☐ Preliminary/Pilot Review
☐ Renewal Review
☑ New Study Implementation Review
☐ Amended Protocol Review on #

IMPORTANT REMINDERS

PROBLEMS OR ADVERSE REACTIONS:
If any problems in the treatment of human subjects or unexpected adverse reactions occur which may be related to this study, you MUST notify an IRB Chairman IMMEDIATELY.

CHANGES IN PROTOCOL:
If there are changes in procedures or changes in the study protocol, you MUST notify the IRB Chairman BEFORE they are implemented unless the changes are for enhancing subject

RENEWAL:
You are required to apply for renewal of approval at least annually for as long as the study is active. Your next review date should be on or before 9/10/2002.

IRB Authorization Signature — Signature Date

JOSEPH M. MANIRE, M.D.
VICE-CHAIRMAN # 2
INSTITUTIONAL REVIEW BOARD

cc: Principal Investigator
IRB Administrator

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Appendix C

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Duke Comprehensive Cancer Center
DUKE UNIVERSITY HEALTH SYSTEM

Protocol Administration

12 September 2006

Isaac Lipkus, PhD
Dept. of Medical Psychiatry
Box 2949 Med Ctr
Durham, NC 27710

Dear Dr. Lipkus:

The Scientific Monitoring Subcommittee at its August 17, 2006 meeting reviewed the audit report on your research study, "The Effects of Informational Displays in Decisions about Tamoxifen Use for Breast Cancer Chemoprevention. (02170 / 3109)."

The full report is attached for your consideration.

At our meeting we addressed the following issues:

- Computer calculation error detected. Subjects were informed of incorrect percentage of risk. Deviation approved by IRB. Subjects affected were contacted by study team and correct information provided.
- The diagnosis code listed in Protrak reported most subjects had breast cancer. After the SMC meeting, the entry was corrected.

The Scientific Monitoring Subcommittee issued a rating of Satisfactory.

Sincerely,

Paul L. Martin, MD, PhD
Chair, Scientific Monitoring Subcommittee

Cc: R. McKinney, MD, Vice Dean for Research
H. Kim Lyerly, Director, DCCC
J. Power, IRB

2424 Erwin Road, Suite 704 • Hock Plaza • Durham, NC 27710 • tel (919) 668-5205 • fax (919) 668-6730

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SUMMARY OF SCIENTIFIC MONITORING FINDINGS

Protocol:	The effects of information displays in decisions about Tamoxifen use for breast cancer chemoprevention.
PI:	Isaac Lipkus, PhD
Research Staff:	Shelly Epps, Michelle Cox (via phone)
Monitors:	Alex Hammett
Cases:	CD0675 (CK), V86484 (SP), D76583 (LB)
Investigator IND?	
Protrak/IRB #:	Protrak # 02170 IRB# 3109
Date of Review:	19 JUL 2006
Transmittal (prelim):	
SMC Report Review:	
Rating:	
Authority:	Paul L. Martin, MD, PhD, Chair

Corrective Plan Required:
Due Date:

PROTOCOL SUMMARY:

The purpose of this study is to test how the numerical format of conveying breast cancer (BC) risk and the risks and benefits of taking Tamoxifen as a chemopreventive agent individually and jointly affect women's intentions to use Tamoxifen and talk to a health care provider about its use. The specific aims are to test how conveying:

AIM1: breast cancer risk as a frequency (e.g., 10 out of 10,000) or probability (e.g., .1%) affects perceived BC risks and negative emotions (e.g., fear, worry) about getting BC, the extent of processing information about Tamoxifen's risks and benefits (i.e., how much time is spent reviewing data on Tamoxifen), and intentions to use and talk to a health care provider about Tamoxifen use.

- AIM2: Tamoxifen's risks and benefits as frequencies or probabilities, individually and jointly interact with the BC risk format to affect women's weighing of the risks and benefits, intentions to use and talk with a health care provider about Tamoxifen use.

2. breast cancer dx vs not

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SUMMARY OF SCIENTIFIC MONITORING FINDINGS

OVERALL SUMMARY OF FINDINGS:

- Protocol expires 15-Oct-2006. Staff is preparing summary report and new Protocol Version for renewal.
- IRB treats small study differently than large studies. Study Summary and protocol are contained within same document. Annual approval letter from IRB does not list all documentation that was reviewed or given approval. This was confirmed via phone with Michelle Cox of IRB.
- Study is procedural only. Study consists of baseline questionnaire completed via mail or telephone screen and a computer lab questionnaire.
- Subjects are considered enrolled if they mail first questionnaire back to study team or give verbal consent over phone.

- Computer calculation error detected. Subjects were informed of incorrect percentage of risk. Deviation approved by IRB. Subjects affected were contacted by study team and correct information provided.
- Study documents not kept in binders. Kept in folders and filing cabinet.
- The wording in the protocol is unclear as to whom will be providing the assessment. Shelly Epps stated that the assessment is done via the computer portion of the study.

3D: Manipulating Format for Communicating Breast Cancer Risk:

Ms. Epps, an experienced genetic counselor within the Duke Breast Cancer High Risk Clinic, who as part of her tasks not only discusses BC risks, but also conveys information about Tamoxifen for chemoprevention, will review all this information with each participant and answer any questions or concerns. After reviewing this information, women's comprehension will be assessed by asking them to repeat their BC risk and state whether it was below, at, or above the threshold to consider Tamoxifen. We will then assess their interest in reviewing information on Tamoxifen (0="not at all" to 6="extremely interested"). Participants will then use the computer to display data on Tamoxifens's risks and benefits.

IRB:

- IRB did not provide detailed report/listing of annual renewal. The approval letter only had the most recent consent listed as indication that the study had been renewed. Michelle Cox of DUHS IRB able to provide clarification and Note To File.
- Ability to view protected health records prior to consent (screening) approved 8/31/04.
- Recruitment letter changed to state the subject's primary provider supported the research study approved 8/16/05.
- Additional sites added to reach enrollment approved 5/18/05.
- Verbal consent Version 2/11/05 approved 3/9/05.
- IRB notified of calculation deviation 2/2004. Deviation approved.

INFORMED CONSENT:

- CD0675 (CK) – eligible. Signed correct consent. Verbal consent given 3/4/05.
- V86484 (SP) – eligible. Signed correct consent. Verbal consent given 3/18/05
- D76583 (LB) – eligible. Signed correct consent. Verbal consent given 8/12/05. Gail % diagnosis not clearly documented.

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SUMMARY OF SCIENTIFIC MONITORING FINDINGS

REGULATORY:

- Regulatory Documents (including Financial Disclosure, Delegation of Responsibility/Signature Log, Monitoring Log, CVs, Medical Licenses, etc…) for all investigators not located in folder.
- Study Responsibility/Signature Log not located in the folder.

STUDY ENDPOINTS:

No endpoints.
Subject has completed study following computer lab assessment and/or 1-month follow-up.

ACCRUAL GOAL:

The goal is to enroll 280-300 subjects.

- Currently 167 subjects have been enrolled as of 17-July-2006.

TYPE of DESIGN/STOPPING RULES:

No stopping rules. Procedural only.

DATA SYSTEMS/QUALITY/AUDIT PREPARATION:

- Calculation error was detected after subjects had been given incorrect percentage of risk. IRB was notified and approved deviation. IRB approved re-contact letter for affected subjects.

ELIGIBILITY:

CD0675 (CK) – eligible.
V86484 (SP) – eligible.
D76583 (LB) – eligible.

TREATMENT DELIVERY:

- V56484 listed as lost to follow-up. Missing 1-month follow-up survey.
- CD0675 indicated she felt informed about Tamoxifen via the study treatment. Believes it greatly reduces chance for breast cancer.
- D76583 indicated she was not confident she had received enough information about Tamoxifen to make an informed decision about its use as treatment.

AE REPORTING:

XII: Process for Reporting of Adverse Events: Unanticipated problems involving risks to subjects or others, serious adverse events related to participation in the study and all subject deaths will be reported to the local IRB using a standard reporting form. They will also be promptly reported by phone (301-619-2165), by mail (hsrrb@det.amedd.army.mil), or by facsimile (301-619-7803) to the Army Surgeon General's Human Subjects Research Review Board (HSRRB). A complete written report, follow the initial telephone call, will be sent to the U.S. Army Medical Research and Materiel Command, ATTN:MCMR-ZB-QH, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

- No AEs/SAEs have been reported. Study is procedural questionnaire only.

OTHER:

PI was present and available during audit.

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Appendix D.1

Private Diagnostic Clinic, PLLC
at DUKE UNIVERSITY MEDICAL CENTER

December 27, 2007

«Exp»
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«Exp1»

Dear Ms. «Last»,

The gynecology clinics at Duke University Health Systems are trying to better educate women about their breast cancer risks, and especially, how to inform and help women make decisions about new medications that can help prevent breast cancer, especially Tamoxifen. We would like for you to be aware of a study that is being conducted by the Risk Communication Lab assessing breast cancer risk and reviewing possible prevention options. If you have had a past diagnosis of breast cancer, this assessment will not be accurate for you. Therefore, you are not eligible to participate in this study. However, we do ask that you please return the Breast Cancer Risk Assessment Survey included with this letter. By returning the Breast Cancer Risk Assessment Survey, research staff will not contact or follow up with you about this research study. In addition, we do apologize if it has been disturbing or upsetting to you in any way to receive this letter. If you are interested in learning more about the research study, please continue reading this letter.

In recent years, a number of clinical studies have shown that Tamoxifen can lower breast cancer in women who may be at an increased risk. Among these women, the decision to use Tamoxifen needs careful thought about the drug's risks and benefits. This research study will look at ways to help women at possibly higher risk of breast cancer make decisions about Tamoxifen use. Women in the research study are NOT being asked to take Tamoxifen. ***Please do not think you are at higher risk merely because you got this letter.***

The first step is to see if you qualify for this research study by assessing your risk of breast cancer. By filling out the enclosed Breast Cancer Risk Assessment questionnaire, research study personnel can assess your breast cancer risk; this can help inform you whether considering medical therapy to lower your risk might be something to think about. This questionnaire information will be kept confidential and will not become part of your medical record at the gynecology clinic unless you discuss the

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questionnaire information with your healthcare provider. Your healthcare provider will not be sent information about your participation in this research study.

If your risk for breast cancer, based on your return mailed Breast Cancer Risk Assessment survey, is such that you qualify for taking Tamoxifen, you will then be contacted by phone and read a verbal consent for the Tamoxifen Baseline Screener. If you choose to voluntarily participate in the research study, you will be asked to take part in a short phone Tamoxifen Baseline Screener survey lasting no more than 15 minutes. Remember, you are NOT being asked to take Tamoxifen to be part of this research study. After the Tamoxifen Baseline Screener survey, you will be asked to come to Brightleaf Square in Durham for an in-person-interview. At the in-person interview you will be given a consent form for the study. If you agree to participate in the research study, during the in-person interview you will be shown your breast cancer risk estimate and information about the risks and benefits of Tamoxifen use, followed by some questions on this information. The in-person session should last no more than an hour. One month after your next scheduled gynecological visit, you will be called by research study personnel one more time for a short 10-minute survey. For your participation in this research study, you will be mailed a check for $40.00.

We hope that you will complete the enclosed Breast Cancer Risk Assessment questionnaire and mail it back in the self-addressed stamped envelope. If we do not receive your questionnaire within two weeks, a member of the research study will call you to see if you are interested in the study, review the study with you and answer any questions you may have. If you are interested at that time, we will complete the Breast cancer Risk Assessment questionnaire over the phone with you. In addition, if study personnel are unable to contact you via phone, we will mail you a reminder postcard regarding this research study.

Through this study, gynecology clinics at Duke University Health System hope to improve how they provide important information to women regarding their health decisions. If you have further questions, please contact Dr. Isaac Lipkus, the principal investigator for the study, at 919-956-5644.

Sincerely,

Duke OB/GYN

Disclaimer: *Your healthcare provider has reviewed the information in the letter about the study. It is your choice to voluntarily participate in the research study. If you choose not to participate in the research study, it will not affect your medical care at Duke University Health System. It is a Duke University Health System's policy to have the participation letter signed by the healthcare provider.*

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Appendix D.2

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

Breast Cancer Risk Assessment Survey

All women that have had breast cancer in the past or have been recently diagnosed with breast cancer, we do ask that you please return the blank Breast Cancer Risk Assessment Survey. By returning the blank Breast Cancer Risk Assessment Survey, research staff will not contact or follow up with you about this research study. Thank you for your time and help with this research study!

We would like to estimate your chance of getting breast cancer, to see if you qualify for this study.

1. What is your age? _____ (write age here)

2. What is your Date of Birth: _____/_____/_____
(Month) (Day) (4-digit year)

Please answer the following questions by placing a ☑ or ☒ in the appropriate box.

3. Which of the following best describes your race or ethnic background?

- ❑ White
- ❑ Hispanic
- ❑ Black
- ❑ Asian or Asian American
- ❑ Hawaiian, Native
- ❑ Native American
- ❑ Asian Indian
- ❑ Filipino
- ❑ Other (specify: _____)
- ❑ Don't know

4. What is your highest level of education?

- ❑ Some high school
- ❑ High school graduate
- ❑ Trade/technical/vocational school
- ❑ Some college
- ❑ College graduate
- ❑ Post graduate work/graduate degree
- ❑ Don't know

5. Do you have any children? ❑ Yes **(☛ go to question 5a)** ❑ No **(☛ skip to question 6)**

5a). *How old were you when you had your first live birth?* _____ (write age here)

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6. How old were you when you had your first menstrual period? ____ (write age here)

❑ Never had a menstrual period
❑ Don't know

7. Was your mother ever told by a doctor that she had breast cancer?

❑ Yes ❑ No ❑ Don't know

8. Do you have any biological sisters (related by blood)?

❑ Yes **(☛ go to question 8a)** ❑ No **(☛ skip to question 9)**

8a) *Were any of your biological sisters ever told that they had breast cancer?*

❑ Yes **(☛ go to question 8b)** ❑ No **(☛ skip to question 9)**

8b) *How many sisters were told they had breast cancer?* _____ (write # here)

9. Do you have any biological daughters (related by blood)?

❑ Yes **(☛ go to question 9a)** ❑ No **(☛ skip to question 10)**

9a) *Were any of your* **biological** *daughters ever told that they had breast cancer?*

❑ Yes **(☛ go to question 9b)** ❑ No **(☛ skip to question 10)**

9b) *How many daughters were told they had breast cancer?* _____ (write # here)

10. Are you currently on hormone replacement therapy? ❑ **Yes** ❑ **No**

11. Have you ever had a hysterectomy? (in other words, *Have you had your uterus surgically removed?)* ❑ Yes ❑ No

A breast biopsy is the surgical removal of a sample of breast tissue to find out if a woman has breast cancer. This does not include an aspiration where a needle is inserted into the breast to remove fluid.

12. Have you ever had a breast biopsy?

❑ **Yes** (☛ go to questions 12a through 12d) ❑ No (☛ skip to question 13)

12a) *How many breast biopsies have you had?* _____ (write # here)

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12b) *Were you ever told that your breast biopsy (or biopsies) was atypical hyperplasia, a benign non-cancerous condition in which breast tissue has certain abnormal features?* ❑ Yes ❑ No ❑ Don't Know

12c) *Were you ever told that your breast biopsy (or biopsies) was lobular carcinoma in situ, also know as LCIS? LCIS is having cancerous cells confined to the lobules of the breast.* ❑ Yes (☛ **skip to question 17)** ❑ No ❑ Don't Know

12d) *Were you ever told that your breast biopsy (or biopsies) was ductal carcinoma in situ, also know as DCIS? DCIS is having cancerous cells confined to the ducts of the breast.* ❑ Yes (☛ **skip to question 17)** ❑ No ❑ Don't Know

13. Have you ever had invasive breast cancer? ❑ Yes (☛ **skip to question 17)** ❑ No ❑ Don't Know

14. Have you participated in the Breast Cancer Prevention Trial (BCPT) or the Study of Tamoxifen and Raloxifene (STAR) Trial? ❑ Yes (☛ **skip to question 17)** ❑ No ❑ **Don't Know**

15. Have you ever taken Tamoxifen, which is also known as Nolvadex? ❑ Yes (☛ **skip to question 17)** ❑ No ❑ Don't Know

16. Are you pregnant now? ❑ Yes ❑ No ❑ Don't Know

17. Thank you for your participation. Do we have your permission to call you with more information about a research study to help women make informed decisions about whether Tamoxifen is right for them to prevent breast cancer? You will NOT be asked to take Tamoxifen.

❑ No ❑ Yes ☛ If yes, please complete information below:

First Name *Last Name*

Address *P.O.Box/ Apt.*

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City State Zip

Daytime #: ( ) - Evening #: ( ) -

Cell phone #: ( ) - Email address:

What are the best days and times for a member of our project staff to contact you?

Thank you for taking the time to complete this survey! ☺

Please mail this survey back in the self-addressed stamped envelope. Once we determine if you are eligible to participate, someone will call you to tell you more about the study. At that time, you can decide if you would like to participate further.

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Appendix D.3

The effects of informational displays in decisions about tamoxifen use for breast cancer chemoprevention

Study Introduction and
*****PHONE*** Screener**
Version 10/13/04

May I please speak with Ms. _____.

My name is _____ and I am with Duke University Medical Center's Cancer Control Research Program. We recently sent you the Breast Cancer Risk Assessment survey in the mail to see if you qualify for our research study about tamoxifen and breast cancer prevention. Did you receive the survey?

1A. ❑ Yes: Did you get a chance to fill it out and return it to us in the mail?

2A. ❑ Yes: When did you return it? _____Thank you! Once we receive it, we'll check to see if you're eligible and if you are eligible we will call you to do a short survey. If we don't receive the survey you mailed within a week, we'll call you back.

2B. ❑ No: Would you be willing to complete the Breast Cancer Risk Assessment screener survey with me over the telephone?

3A. ❑ Yes: Thank you! I'll begin by telling you a little about the study. (if participant asks to schedule for a later time, record time for call back and begin with INTRO when called, otherwise go to INTRO now)

3B. ❑ No: Well, I appreciate your time today. If you would like to participate in the study at a later date, please call us at 919-956-5644. Have a great day!

1B. ❑ No: Can I take a moment of your time to tell you about the study?

4A. ❑ Yes: Thank you! (if participant asks to schedule for a later time, record time for call back and begin with INTRO when called, otherwise go to INTRO now)

4B. ❑ No: Well, I appreciate your time today. If you would like to receive information about the study at a later date, please call us at 919-956-5644. Have a great day!

The gynecology clinics at Duke University Medical Center are trying to better educate women about their breast cancer risks, and especially, how to inform and help women make decisions about new medications that can help prevent breast cancer, especially Tamoxifen. We would like to ask you to be evaluated for a research study assessing breast cancer risk and reviewing possible prevention options. In recent years, a number of clinical studies have shown that Tamoxifen can lower breast cancer in women who may be at increased risk. Among these women, the decision to use Tamoxifen needs careful thought about the drug's risks and benefits. This study will look at ways to help women at possibly higher risk of breast cancer make decisions about Tamoxifen use. Women in the study are NOT being asked to take Tamoxifen.

The first step is to see if you qualify for this study by assessing your risk of breast cancer. This can help inform you whether considering medical therapy to lower your risk might be something to think about. This information will be kept confidential and will not become part of your medical record at the gynecology clinic unless you discuss it with your healthcare provider. Your healthcare provider will not be sent information about

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your participation in this study. If your risk for breast cancer is such that you qualify for taking Tamoxifen, you will then be asked to participate in the research study and will be asked to take part in a short phone survey lasting no more than 15 minutes. After the survey, you will be asked to come to Brightleaf Square in Durham where you will be shown your breast cancer risk estimate and information about the risks and benefits of Tamoxifen use, followed by some questions on this information. The in-person session should last no more than an hour. One month after your next scheduled gynecological visit, you will be called one more time for a short 10-minute survey. For your participation in this study, you will be mailed a check for $40.00. Does this sound like something you would be interested in?

❑ ***Yes*** *Great! Let me get your name and phone # for our records. This information will be kept only if you become enrolled in the study.* ***(Go to Caller Information Sheet)*** ***THEN say, "****I'm going to ask you the questions from the survey now to see if you qualify and if you do, someone will call you back to administer the 15-minute telephone survey****(Go to Breast Cancer Risk Assessment screener)***

❑ ***No: Would you like to be considered for future studies?***

❑ **Yes:** Complete Interest in Future Studies FORM

❑ No: Well, thank you for your time and interest.
Have a great day!

WHEN SCREENER IS COMPLETED

Again, thank you for you time. I'll have a research staff member look this information over to see if you qualify for the study. If you do, she will call you back within a few days to do a verbal consent for the Tamoxifen Baseline survey. If you do not qualify for the research study, we will not re-contact you by telephone. Have a great day!

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

Breast Cancer Risk Assessment Survey

We would like to estimate your chance of getting breast cancer, to see if you qualify for this study.

1. What is your age? _____ (write age here)

2. What is your Date of Birth: _____/_____/_____
(Month) (Day) (4-digit year)

Please answer the following questions by placing a ☑ or ☒ in the appropriate box.

3. Which of the following best describes your race or ethnic background?

❑ White ❑ Native American

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❑ Hispanic ❑ Asian Indian
❑ Black ❑ Filipino
❑ Asian or Asian American ❑ Other (specify:)
❑ Hawaiian, Native ❑ Don't know

4. What is your highest level of education?

❑ Some high school ❑ College graduate
❑ High school graduate ❑ Post graduate work/graduate degree
❑ Trade/technical/vocational school ❑ Don't know
❑ Some college

5. Do you have any children? ❑ Yes **(☛ go to question 5a)** ❑ No **(☛ skip to question 6)**

5a). *How old were you when you had your first live birth?* _____ (write age here)

6. How old were you when you had your first menstrual period? ____ (write age here)

❑ Never had a menstrual period
❑ Don't know

7. Was your mother ever told by a doctor that she had breast cancer?

❑ Yes ❑ No ❑ Don't know

8. Do you have any biological sisters (related by blood)?

❑ Yes **(☛ go to question 8a)** ❑ No **(☛ skip to question 9)**

8a) *Were any of your biological sisters ever told that they had breast cancer?*

❑ Yes **(☛ go to question 8b)** ❑ No **(☛ skip to question 9)**

8b) *How many sisters were told they had breast cancer?* _____ (write # here)

9. Do you have any biological daughters (related by blood)?

❑ Yes **(☛ go to question 9a)** ❑ No **(☛ skip to question 10)**

9a) *Were any of your biological daughters ever told that they had breast cancer?*

❑ Yes **(☛ go to question 9b)** ❑ No **(☛ skip to question 10)**

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9b) *How many daughters were told they had breast cancer?* _____ (write # here)

10. Are you currently on hormone replacement therapy? ❑ **Yes** ❑ **No**

11. Have you ever had a hysterectomy? (in other words, ❑ Yes ❑ No
Have you had your uterus surgically removed?)

A breast biopsy is the surgical removal of a sample of breast tissue to find out if a woman has breast cancer. This does not include an aspiration where a needle is inserted into the breast to remove fluid.

12. Have you ever had a breast biopsy?

❑ **Yes** (☛ go to questions 12a through 12d) ❑ No (☛ skip to question 13)

12a) *How many breast biopsies have you had?* _____ (write # here)

12b) *Were you ever told that your breast biopsy* ❑ Yes
(or biopsies) was atypical hyperplasia, ❑ No
a benign non-cancerous condition in which ❑ Don't Know
breast tissue has certain abnormal features? _____

12c) *Were you ever told that your breast biopsy* ❑ Yes **(☛ skip to question 17)**
(or biopsies) was lobular carcinoma in situ, ❑ No
also know as LCIS? LCIS is having cancerous ❑ Don't Know
cells confined to the lobules of the breast. _____

12d) *Were you ever told that your breast biopsy* ❑ Yes **(☛ skip to question 17)**
(or biopsies) was ductal carcinoma in situ, ❑ No
also know as DCIS? DCIS is having cancerous ❑ Don't Know
cells confined to the ducts of the breast. _____

13. Have you ever had invasive breast cancer? ❑ Yes **(☛ skip to question 17)**
❑ No
❑ Don't Know

16. Have you participated in the Breast Cancer Prevention Trial (BCPT) or the Study of Tamoxifen and Raloxifene (STAR) Trial? ❑ Yes **(☛ skip to question 17)** ❑ No ❑ **Don't Know**

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17. Have you ever taken Tamoxifen, which is also known as Nolvadex? ❑ Yes (☛ **skip to question 17**)
❑ No
❑ Don't Know

16. Are you pregnant now? ❑ Yes
❑ No
❑ Don't Know

17. Thank you for your participation. Do we have your permission to call you with more information about a research study to help women make informed decisions about whether Tamoxifen is right for them to prevent breast cancer? You will NOT be asked to take Tamoxifen.

❑ No ❑ Yes ☛ If yes, please complete information below:

First Name *Last Name*

Address *P.O.Box/ Apt.*

City *State* *Zip*

Daytime #: ( ) - *Evening #: ( ) -*

Cell phone #: ( ) - *Email address:*

What are the best days and times for a member of our project staff to contact you?

Thank you for taking the time to complete this survey! ☺

Please mail this survey back in the self-addressed stamped envelope. Once we determine if you are eligible to participate, someone will call you to tell you more about the study. At that time, you can decide if you would like to participate further.

Duke University Risk Communication Lab
905 West Main Street, Suite 24D
Durham, NC 27701

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Appendix D.4

Baseline Date: _____
Interviewer: _____

5 year breast cancer risk (Gail score) _____

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

Verbal Consent and Tamoxifen Baseline Questionnaire

Hello, may I speak to _____. My name is _____ and I am calling from Duke University Medical Center. You recently responded to a short questionnaire expressing your interest in being part of a research study about new drugs to prevent breast cancer. I am calling you to see if this was a good time to tell you more about the project?

❑ No (but still interested)

☛ When would be a better day and/or time for someone to call you back?

_____

(Record call back date and time here)

☛ Great, let me now get your contact information for our records.

☛ Go to Caller Contact Sheet--record scheduled call back day and time.

❑ No (no longer interested)

☛Would you like to be considered for future studies?

❑ Yes ☛ If yes, complete an "Interested in Future Studies" Form.

❑ No ☛ Well, thank you for your time and have a nice day.

❑ Yes

☛Great! Let me start by telling you a little bit about this project.

* Go to Verbal Consent on next page.

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Verbal Consent

Yes * Great! Before we go any further, I need to tell you a little more about the research project. We are doing these interviews as part of a large health education project headed by researchers at Duke University Medical Center with funding from the US Department of Defense. We want to learn more about what women think about their chances of getting breast cancer and new drugs to prevent breast cancer. We are asking women to review information about their chances of getting breast cancer and to look at materials about Tamoxifen, a drug used to prevent breast cancer.

If you agree to become part of this research study, we will ask you first to complete a 15-20 minute phone interview. We will then schedule a time for you to come into our office here at Brightleaf Square in Downtown Durham for a one-hour interview. At this time, you will answer a series of questions that will ask your opinions about taking drugs to prevent breast cancer, and about taking one drug, Tamoxifen, in particular. You will get information about your risk of getting breast cancer. In addition, you will be called one-month after your gynecological appointment and will be asked questions about your perceptions of breast cancer risk and about Tamoxifen. You do **NOT** need to take any medications to be in this study or undergo any medical procedures.

There are no physical risks associated with this research study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this can not be guaranteed. Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke University Health System Institutional Review Board or the US Department of Defense.

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any question and you may take a break at any time during the study. You may stop your participation in this study at any time. There are no costs involved with the study other than the time spent answering the questionnaires and evaluating study materials.

If you agree to be interviewed, please know that your participation is voluntary. You have the right to refuse to participate in any part of the study and can stop being interviewed at any time without penalty. You have the right to refuse to answer any questions. Your answers will be confidential. To protect your privacy, we will assign you a unique identification number. We will store all your answers only with that number and not with your name. Only trained project staff will have access to your answers. We will make every effort to protect your identity. You will not be identified in any report or publication of this project or its results.

Our project manager is Lisa Werner. She's the person to contact if you want to withdraw from the project or have questions at any time. You can email her at Lisa.Werner@duke.edu or call her at 919-956-5644. You may also contact Dr. Isaac Lipkus, Principal Investigator, at the same number.

This project has been reviewed and approved by a group that makes sure that project participants are treated fairly and protected. If you have any questions about your rights as a project participant, or are dissatisfied at any time with any part of this project, you may contact the Duke University Health System Institutional Review Board (IRB) at (919) 668-5111.

We will pay you $40.00 for completing all parts of this study.

Do you have any questions?
❑ **Yes**
❑ **No**

Does this sound like something you'd be interested in?
❑ **Yes**
❑ **No**

- Are you willing to take part in this telephone interview?

❑ **Yes** Ok, now I will be reading the statement of consent to you.
❑ **No**

If not willing to participate, ask:

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- Do you have any questions I can answer about the project?

-Yes

If yes, answer questions and ask to participate again.

-No

If no, thank the woman for her time and consideration and hang up.

STATEMENT OF CONSENT

The purpose of this study, procedures to be followed, risks and benefits have been explained to you. You have been allowed to ask questions and your questions have been answered to your satisfaction. You have been told whom to contact if you have additional questions. You have been read this consent form and agree to be in this study with the understanding that you may withdraw at any time. You have been told that you will be given a signed copy of this consent form. ***You understand that your name, mailing address, and social security number will be submitted to the Duke University Medical Center's Accounting Department so that you may receive a check for your participation.***

Do you agree with the Statement of Consent I've just read, and therefore give your verbal consent to participate in this study?

❑Yes ☛ Complete information below and proceed with baseline survey.

❑No ☛ Thank woman for her time and finish call.

_____ _____/_____/_____

Name of Subject (Print) **Date of Verbal Consent**

_____

Address of Subject City State Zip Code

___ __ ___ - ___ _ - ____

Subject's Social Security Number

_____

Name of Person Obtaining Verbal Consent Signature of Person Obtaining Verbal Consent

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Deleted: **If yes:** Ok. I'd also like to give you some project telephone numbers and addresses. You may want to get a pen or pencil to write them down. Our project manager is Lisa Werner. She's the person to contact if you want to withdraw from the project or have questions at any time. You can email her at Lisa.Werner@duke.edu or call her at 919-956-5644. You may also contact Dr. Isaac Lipkus, Principal Investigator, at the same number.¶
¶
This project has been reviewed and approved by a group that makes sure that project participants are treated fairly and protected. If you have any questions about your rights as a project participant, or are dissatisfied at any time with any part of this project, you may contact the Duke University Health System Institutional Review Board (IRB) at (919) 668-5111.¶
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Tamoxifen Baseline Questionnaire

Section A: Risk Perceptions

I will now ask your thoughts and feelings about getting breast cancer. For the first few questions, I will ask for your chances of getting breast cancer at different time frames.

1. What do you think is your chance of getting breast cancer in the **next 5 years**, would you say…? (Read choices and place a checkmark (x) or (√) next to the respondent's answer.

1 No chance
2 Very unlikely
3 Unlikely
4 Likely
5 Very Likely
6 Certain to happen
8 DON'T KNOW
9 REFUSED

2a. On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is **your** chance of getting breast cancer within the next 5 years?

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Put answer here
(if they say 50%, then ask * 2b**) What do you mean by 50% chance? Would you say….**
1 I am equally as likely to get or not get breast cancer
2 I am at average risk
3 Other? 2c) (explain)
8 DON'T KNOW
9 REFUSED

998 DON'T KNOW
999 REFUSED

3. Compared to other women your age and race, your chance of getting breast cancer in the next 5 years is….

1 Much below average
2 Below average
3 Same average risk as women your age and race
4 Above average
5 Much above average
8 DON'T KNOW
9 REFUSD

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4. What do you think is your chance of getting breast cancer **in your lifetime**, would you say…? (Read choices and place a checkmark (x) or (√) next to the respondent's answer.

1 No chance
2 Very unlikely
3 Unlikely
4 Likely
5 Very Likely
6 Certain to happen
8 DON'T KNOW
9 REFUSED

5a. On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is **your** chance of getting breast cancer in your lifetime?

Put answer here
(if they say 50%, then ask * 5b**) What do you mean by 50% chance? Would you say….**

1 I am equally as likely to get or not get breast cancer
2 I am at average risk
3 Other? 5c) (explain)
8 DON'T KNOW
9 REFUSED

998 DON'T KNOW
999 REFUSED

6. Compared to other women your age and race, your chance of getting breast cancer in your lifetime is….

1 Much below average
2 Below average
3 Same average risk as women your age and race
4 Above average
5 Much above average
8 DON'T KNOW
9 REFUSED

7. Now think of 100 women your age and race who are identical to you in all ways. Hence, their chance of getting breast cancer is exactly the same as yours. Out of these 100 women, how many do you think will get breast cancer during the next five years?

Put answer here
998 DON'T KNOW
999 REFUSED

8. Out of these 100 women, how many do you think will get breast cancer during their lifetime?

Put answer here
998 DON'T KNOW
999 REFUSED

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9. How **worried** are you about getting breast cancer in the next 5 years? Would you say….

1 Not at all worried
2 Slightly worried
3 Somewhat worried
4 Very worried
5 Extremely worried
8 DON'T KNOW
9 REFUSED

10. How **worried** are you about getting breast cancer in your lifetime? Would you say….

1 Not at all worried
2 Slightly worried
3 Somewhat worried
4 Very worried
5 Extremely worried
8 DON'T KNOW
9 REFUSED

11. How **fearful** are you about getting breast cancer in the next 5 years? Would you say….

1 Not at all fearful
2 Slightly fearful
3 Somewhat fearful
4 Very fearful
5 Extremely fearful
8 DON'T KNOW
9 REFUSED

12. How **fearful** are you about getting breast cancer in your lifetime? Would you say…

1 Not at all fearful
2 Slightly fearful
3 Somewhat fearful
4 Very fearful
5 Extremely fearful
8 DON'T KNOW
9 REFUSED

13. As I mentioned, as part of this study you will be given information about your chance of getting breast cancer. A woman can be informed of her breast cancer risk in different ways. Her risk can be communicated 1) ***verbally***, for example being told that she is at low, average or high risk, or 2) **numerically**, for example being told that her risk is 5%, 25%, 60% and so forth. If we were to inform you of your breast cancer risk, would you prefer it being communicated to you verbally, numerically, both verbally and numerically, or do you not have a preference?

1 Verbally
2 Numerically
3 Prefer both verbally and numerically
4 No preference
8 DON'T KNOW
9 REFUSED

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Section B

Instructions: I would now like to ask a few questions about Tamoxifen, a drug that has been shown to reduce the risk of breast cancer.

14. Have you ever heard of Tamoxifen?

1 Yes
5 No
8 DON'T KNOW
9 REFUSED

15. Tamoxifen is used for the prevention or for the treatment of breast cancer. For the following question, only think of women who have **never** been treated for breast cancer. Have you ever known of someone who took Tamoxifen to prevent breast cancer?

1 Yes
5 No
8 DON'T KNOW
9 REFUSED

16. Have you ever seen a TV commercial on using Tamoxifen to prevent breast cancer?

1 Yes
5 No
8 DON'T KNOW
9 REFUSED

17. Have you ever read an article on using Tamoxifen to prevent breast cancer?

1 Yes
5 No
8 DON'T KNOW
9 REFUSED

18. Have you ever heard about Tamoxifen on the radio?

1 Yes
5 No
8 DON'T KNOW
9 REFUSED

19. Have you ever heard about Tamoxifen from a friend?

1 Yes
5 No
8 DON'T KNOW
9 REFUSED

20. Overall, how effective do you think Tamoxifen is at preventing breast cancer? Would you say…

1 Not at all effective
2 Slightly effective
3 Somewhat effective
4 Very effective
5 Extremely effective
8 DON'T KNOW
9 REFUSED

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21. As with most drugs, there are some medical benefits and medical risks (e.g. side effects). For the next question, we want you to think about the overall benefits and risks related to taking Tamoxifen for a period of five years. We realize that you may not know all the benefits and risks, but we would like to know what you think. Overall, do you think that the…..

1 Benefits outweigh the risks by a lot
2 Benefits outweigh the risks by a little
3 Benefits and risks cancel each other out
4 Risks outweigh the benefits by a little
5 Risks outweigh the benefits by a lot

8 DON'T KNOW
9 REFUSED

22. According to the U.S. Food and Drug administration, Tamoxifen can only be given to women who have a high enough level of breast cancer risk. Do you think your level of breast cancer risk during the next five years is high enough to qualify you to take Tamoxifen to prevent breast cancer?

1 Yes
5 No

8 DON'T KNOW
9 REFUSED

23. How interested are you in talking to a health care provider about taking Tamoxifen? Would you say….

1 Not at all interested
2 Slightly interested
3 Somewhat interested
4 Very Interested
5 Extremely interested

8 DON'T KNOW
9 REFUSED

24. How motivated are you to talk to a health care provider about taking Tamoxifen? Would you say….

1 Not at all motivated
2 Slightly motivated
3 Somewhat motivated
4 Very motivated
5 Extremely motivated

8 DON'T KNOW
9 REFUSED

25. If you were to consider taking Tamoxifen to prevent breast cancer, would you want the decision to be made….

1 by your doctor
2 by you
3 equally between you and your doctor

8 DON'T KNOW
9 REFUSED

26. How interested are you in taking Tamoxifen? Would you say….

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1 Not at all interested
2 Slightly interested
3 Somewhat interested
4 Very Interested
5 Extremely interested
8 DON'T KNOW
9 REFUSED

27. How confident are you that you can now make a decision about whether taking Tamoxifen is right for you? Would you say…..

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1 Not at all confident
2 Slightly confident
3 Somewhat confident
4 Very confident
5 Extremely confident
8 DON'T KNOW
9 REFUSED

28. Overall, do you think you have enough information to decide whether taking Tamoxifen is right for you?

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1 Yes
5 No
8 DON'T KNOW
9 REFUSED

29. What would keep you from taking Tamoxifen to prevent breast cancer?

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8 DON'T KNOW
9 REFUSED

30. Do you currently smoke cigarettes?

1 Yes
5 No
8 DON'T KNOW
9 REFUSED

Closing

Those are all the questions I have for now. Thank you so much for taking the time to complete this interview. I would now like to take a moment to schedule a time for you to come into our office for your face-to-face interview. But, first let me verify your contact information.

Go to Caller Information Sheet

Study ID#:_____

Appendix D.5

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Now we're finally ready to start the survey! ¶
¶
BEGIN Baseline SURVEY¶
¶
If not a good time to complete the survey: What is a good time for us to call you back?¶
¶
If does not have time for survey now, record time and date of call back time and file. Then thank the subject and hang up.¶
¶
¶
¶
Section Break (Continuous)
Baseline Questionnaire¶
¶
¶
Section A: Risk Perceptions¶
¶
I will now ask your thoughts and feelings about getting breast cancer. For the first few questions, I will ask for your chances of getting breast cancer at different time frames.¶
¶
1. What do you think is your chance of getting breast cancer in the **next 5 years**, would you say…? (Read choices and place a checkmark (x) or (√) next to the respondent's answer.¶
¶
1____ No chance¶
2____ Very unlikely¶
3____ Unlikely¶
4____ Likely¶
5____ Very Likely¶
6____ Certain to happen¶
8____ DON'T KNOW ¶
9____ REFUSED ¶
¶
On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is **your** chance of getting breast cancer within the next 5 years?¶
¶
_____ Put answer here ¶
(**if they say 50**%, then ask * 2b**) What do you mean by 50% chance? Would you say….**¶
1____ I am equally as likely to get or not get breast cancer¶
2____ I am at average risk¶
3____
Other? 2c) (explain ... [236]

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INTRODUCTION AND PURPOSE

Duke University Comprehensive Cancer Center is conducting a research study to learn more about how best to communicate the risks and benefits of taking Tamoxifen, which is a medication that may help prevent breast cancer in some women. We hope to study how women make decisions about Tamoxifen, and what type of information can best help women to talk to their doctor and to make an informed decision about whether Tamoxifen is right for them. The Principal Investigator on this research study is Dr. Isaac Lipkus. This study is being sponsored by a grant from the U. S. Department of Defense (US DOD). Portions of Dr. Lipkus' and his research team's salaries are being paid by this grant.

WHO IS ASKED TO PARTICIPATE IN THS STUDY?

Our goal is to recruit 300 women into the study who are not pregnant, have not previously taken tamoxifen, have not participated in the Study of Tamoxifen and Raloxifene (STAR) prevention trial, have not had a prior diagnosis of invasive or non-invasive breast cancer and whose 5-year level of breast cancer risk is such that they would be considered to take tamoxifen. Based on your responses to the Breast Cancer Risk Assessment Survey, you are eligible to participate in this study. You are NOT being asked to take tamoxifen to be a part of this study.

Deleted: . The Principal Investigator on this study is Dr. Isaac Lipkus. This study is being sponsored by a grant from the U. S. Department of Defense (US DOD). Portions of Dr. Lipkus' and his research team's salaries are being paid by this grant.

PROCEDURES

Your participation in this research study involves three steps. You have completed **step one**, in which you gave verbal consent for the Tamoxifen Baseline Questionnaire by phone interview with questions about: 1) your knowledge of breast cancer prevention and Tamoxifen, 2) what you see as the risks and benefits of taking Tamoxifen, and 3) what you think about your own risk of getting breast cancer. In addition you answered questions about the history of breast cancer in your family, and other various questions needed to assess your level of breast cancer risk.

In **step two**, you will be asked participate in a one hour face-to-face interview at the Risk Communication Laboratory at Brightleaf Square in Durham or a research staff member will do an in person lab with you at your home. During the interview we will review with you your lifetime chance of getting breast cancer. This information will be based on the answers that you gave us during the phone interview. We will ask you to review web-based materials created especially for you about your risk of getting breast cancer in your lifetime and about the general health risks and benefits of taking Tamoxifen for five years. We will then ask you to complete a series of web-based and written questionnaires that will assess your reactions to these materials by asking a variety of questions about breast cancer, breast cancer prevention and Tamoxifen.

In **step three**, one month after your gynecology appointment at Duke University Medical Center's OB/GYN clinic, you will be asked to complete a 10-15 minute telephone follow-up survey. This survey will ask you questions similar to those asked during the telephone and face to face interviews. In addition, we will ask whether you talked to your gynecologist or any other doctor about Tamoxifen, and if so, we will ask you questions about what you discussed and what, if any, recommendations were offered.

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Some participants, after completing Steps 2 or 3 above may wish to discuss taking tamoxifen with their health care provider. These participants will be then referred to a tamoxifen specialist. This referral is separate and is not covered under participation in the research study. Participation in the research study ends with the completion of step three.

Compensation

All study-related costs associated with your being in this research study will be paid by the US Department of Defense. If you complete all aspects of the study, you will receive $40 ($5 for completing the baseline telephone survey, $30 for completing the face-to-face interview and $5 for returning the one month follow-up telephone survey). Other than medical care that may be provided and any other payment specifically stated in this consent form, there is no other compensation available to you for your participation in this research.

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Risks

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There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this can not be

guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

There are no costs involved with the study other than the time spent answering the questionnaires and evaluating study materials. You may skip survey questions that you do not want to answer. If at any time, you have any questions, please contact Dr. Isaac Lipkus, at 919-956-5644.

Benefits

While you will not directly benefit from this study, your efforts will hopefully improve the ways we communicate information about the benefits and risks of Tamoxifen.

RIGHT TO WITHDRAW

You may choose not to be in the research study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for research study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

You may withdraw your authorization for us to use all data (other than data needed to report an adverse event or to keep track of your withdrawal) that have already been collected, but you must do this in writing.

Your decision not to participate in this study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke healthcare providers to provide monetary compensation or free medical care to you in the event of a study-related injury.

If you do decide to withdraw, we ask that you contact Dr. Lipkus in writing and let him know that you are withdrawing from the study. His mailing address is: 905 West Main Street, Box 34, Durham, NC 27701. At that time we will ask your permission to continue using all information about you that has already been collected as part of the study prior to your withdrawal.

CONFIDENTIALITY

Study records that identify you will be kept confidential as required by law. Electronic data will be secured with password-protected computer files, and will be deleted after all of the data have been analyzed for publication. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Isaac Lipkus' office at Brightleaf Square separate from study records.

Who will have access to my study records and to whom information may be disclosed?

As part of the study, Dr. Lipkus and his study team will report the results of this study to the US DOD. However, no one will be able to identify you in any way from these records. After the completion of the study, you will not be contacted by any of the study team, by DOD, or anyone else because of your participation in this study. Your records may be reviewed in order to meet federal or state regulations or if an adverse event should occur. Reviewers may include representatives of DOD and the Duke University Health System Institutional Review Board. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

This information will not become part of your medical record at the gynecology clinic unless you discuss it with your healthcare provider. Your healthcare provider will not be sent information about your participation in this study.

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Study ID#: _____

Expiration date or event for the retention of records

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

The sponsor may share data

This information may be further disclosed by the sponsor of this study, [US DOD]. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations.

Who do I call if I have questions about the study or about my rights as a research participant?

If at any time you have questions about the study, please contact Dr. Isaac Lipkus at (919) 956-5644. Should you have any questions as to what your rights are as a participant in this study, you may call the Duke University Health System Institutional Review Board (IRB) at (919) 668-5111.

Statement of Consent

"The purpose of this study, the procedures to be followed, and the risks and benefits of participating have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I have had the consent form read to me, and I agree to be in the study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed copy of this consent form. I understand that my name, mailing address, and social security number will be submitted to the Duke University Medical Center's Accounting Department so that I may receive a check for my participation."

By completing and signing the information below, you agree to the above statement of consent, and therefore, give your written consent to participate in this study.

_____

Name of Subject (please print) Signature of Subject

_____/_____/_____

Date of Consent

_____,_____

Address of Subject City State Zip Code

_____-_____-_____

Subject's Social Security Number

IMPORTANT: In order to receive compensation for your participation in this study, please complete the **CONSENT FOR PAYMENT FORM** on the next page.

_____

Name of Person Obtaining Written Consent Signature of Person Obtaining Written Consent

Appendix D.6.1

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

Instructions: The statements below are about how people think about different tasks. Please tell us how characteristic each statement is about you, using a scale from 1 to 5 **where 1= "extremely *un*characteristic of me" and 5 = "extremely characteristic of me."**

1. ___ I would prefer complex to simple problems.
2. ___ I like to have the responsibility of handling a situation that requires a lot of thinking.
3. ___ Thinking is not my idea of fun.
4. ___ I would rather do something that requires little thought than something that is sure to challenge my thinking abilities.
5. ___ I try to anticipate and avoid situations where there is a likely chance I will have to think in depth about something.
6. ___ I find satisfaction in deliberating hard for long hours.
7. ___ I only think as hard as I have to.
8. ___ I prefer to think about small, daily projects rather than long-term ones.
9. ___ I like tasks that require little thought once I've learned them.
10. ___ The idea of relying on thought to make my way to the top appeals to me.
11. ___ I really enjoy a task that involves coming up with new solutions to problems.
12. ___ Learning new ways to think doesn't excite me very much.
13. ___ I prefer my life to be filled with puzzles that I must solve.
14. ___ The notion of thinking abstractly is appealing to me.
15. ___ I would prefer a task that is intellectual, difficult, and important to one that is somewhat important, but does not require much thought.

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16. ___ I feel relief rather than satisfaction after completing a task that requires a lot of mental effort.

17. ___ It's enough for me that something gets the job done; I don't care how or why it works.

18. ___ I usually end up deliberating about issues even when they do not affect me personally.

Study ID#: _____

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Appendix D.6.2

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

Deleted: Numeracy Questionnaire¶

INSTRUCTIONS: Please tell us how much anxiety you would experience having to do each of the activities below. Please place a checkmark (√) or (X) next to your answer.

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How anxious would you be …

1. Reading a cash register receipt after your purchase.

   1____ Not at all
   2____ A little
   3____ A fair amount
   4____ Much
   5____ Very much

2. Being given a set of numerical problems involving addition to solve on paper.

   1____ Not at all
   2____ A little
   3____ A fair amount
   4____ Much
   5____ Very much

3. Being given a set of subtraction problems to solve.

   1____ Not at all
   2____ A little
   3____ A fair amount
   4____ Much
   5____ Very much

4. Being given a set of multiplication problems to solve.

   1____ Not at all
   2____ A little
   3____ A fair amount
   4____ Much
   5____ Very much

5. Being given a set of division problems to solve.

   1____ Not at all
   2____ A little
   3____ A fair amount
   4____ Much
   5____ Very much

Study ID#: _____

6. When you are reading and you come to a sentence with numbers in it, do you skip over it? Please circle a number from 1-5.

Never Sometimes Always
1----------2----------3----------4----------5

7. Are you comfortable with numbers? Please circle a number from 1-5.

Never Sometimes Always
1----------2----------3----------4----------5

8. Do you feel numbers are too often used by other people to argue for what is in their interest, not in yours? Please circle a number from 1-5.

Never Sometimes Always
1----------2----------3----------4----------5

9. Do you like to look at graphs? Please circle a number from 1-5.

Never Sometimes Always
1----------2----------3----------4----------5

10. How would you characterize yourself? Please circle a number from 1-5.

Someone who hates numbers Someone who loves numbers
1----------2----------3----------4----------5

Numeracy Questionnaire

Instructions: Health professionals often talk about a person's chances of getting diseases by using numbers. Therefore, it is important to understand how people think and use numbers. Please answer the following questions below.

For the first question, we will ask you to estimate how many times something would happen in 1,000 tries. Please give us your best estimate, even if you think your estimate is only a guess.

Example: **Q.** Imagine that we flip a coin 1,000 times. Out of 1,000 flips, how many times do you think the coin would come up heads?

A. *500* out of 1,000

Question 11: Imagine that we roll a fair, six-sided die 1,000 times. Out of 1,000 rolls, how many times do you think the die would come up even (numbers 2, 4, or 6)?

_____ out of 1,000

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Question 12: Please consider the following situation:

In the BIG BUCKS LOTTERY, the chances of winning a $10.00 prize is 1%. What is your best guess about how many people would win a $10.00 prize if 1,000 people each buy a single ticket to BIG BUCKS?

_____ person(s) out of 1,000

Question 13: Please consider the following situation:

In the ACME PUBLISHING SWEEPSTAKES, the chance of winning a car is 1 in 1,000. What percent of tickets to ACME PUBLISHING SWEEPSTAKES win a car?

_____ %

Question 14: Which of the following numbers represents the biggest risk of getting a disease? Please place a checkmark (√) or (X) next to your answer.

_____ 1in 100
_____ 1in 1000
_____ 1 in 10

Question 15: Which of the following numbers represents the biggest risk of getting a disease? Please place a checkmark (√) or (X) next to your answer.

_____ 1%
_____ 10%
_____ 5%

Question 16: If Person A's risk of getting a disease is 1% in ten years, and person B's risk is double that of A's, what is B's risk?

Person B's risk is: _____ %

Question 17: If Person A's chance of getting a disease is 1 in 100 in ten years, and person B's risk is double that of A's, what is B's risk?

Person B's risk is: _____ out of 100.

Question 18: If the chance of getting a disease is 10%, how many people on average would be expected to get the disease:

a). Out of 100: _____

b.) Out of 1000: _____

Question 19: If the chance of getting a disease is 20 out of 100, this would be the same as having a

_____ % chance of getting the disease.

Question 20: The chance of getting a viral infection is .0005. Out of 10,000 people, about how many of them are expected to get infected?

_____ People

Study ID#: _____

Appendix D.6.3

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

Instructions. Please read each statement carefully and indicate on the line to the left of each statement whether you agree or disagree with it. Use the following scale.

1 = strongly agree
2 = somewhat agree
3 = somewhat disagree
4 = strongly disagree

1. _____ If I think something unpleasant is going to happen, I usually get pretty "worked up."
2. _____ I worry about making mistakes.
3. _____ Criticism or scolding hurts me quite a bit.
4. _____ I feel pretty worried or upset when I think or know somebody is angry at me.
5. _____ Even if something bad is about to happen to me, I rarely experience fear or nervousness.
6. _____ I feel worried when I think I have done poorly at something.
7. _____ I have very few fears compared to my friends.

Study ID#: _____

Appendix D.6.4

Reactions to Breast Cancer Risk Feedback

Section A:

(To be asked of women after getting their breast cancer risk on the computer but before seeing the risks and benefits of Tamoxifen)

Instructions: Please answer the following questions about the information you were given about your chance of getting breast cancer during the next five years.

A1. Based on the information we gave you, what is your chance of getting breast cancer during the next five years?

_____ % or _____ out of 10,000

A2. In your opinion, how accurate is the information presented to you about your chance of getting breast cancer? Circle a number between 0 and 6, where 0 is "not at all accurate" and 6 is "completely accurate".

Not at all accurate 0 1 2 3 4 5 6 Completely accurate

A3. In your opinion, how credible, that is believable, is the information presented to you about your chance of getting breast cancer? Circle a number between 0 and 6 where 0 is "not at all credible" and 6 is "completely credible".

Not at all credible 0 1 2 3 4 5 6 Completely credible

A4. In your opinion, how trustworthy is the information about your chance of getting breast cancer? Circle a number between 0 and 6 where 0 is :not at all trustworthy", and 6 is "completely trustworthy".

Not at all trustworthy 0 1 2 3 4 5 6 Completely Trustworthy

A5. How useful was the information about your chance of getting breast cancer? Circle a number between 0 and 6 where 0 is "not at all useful" and 6 is "extremely useful".

Not at all useful 0 1 2 3 4 5 6 Extremely useful

A6. How understandable was the information about your chance of getting breast cancer? Circle a number between 0 and 6 where 0 is "not at all understandable" and 6 is "completely understandable".

Not at all Understandable 0 1 2 3 4 5 6 Completely Understandable

A7. Overall, you found the information about your breast cancer risk to be: Please circle a number from 0 to 6.

a.	Insignificant	0	1	2	3	4	5	6	Significant
b.	Unimportant	0	1	2	3	4	5	6	important
c.	Of no Concern	0	1	2	3	4	5	6	Of much Concern
d.	Means Nothing	0	1	2	3	4	5	6	Means a lot
e.	Irrelevant	0	1	2	3	4	5	6	Relevant
f.	Does not0 matter to me	1	2	3	4	5	6	Does matter to me	

A8. What do you think is your chance of getting breast cancer in the next 5 years. Please place a checkmark (√) or (X7) next to your answer.

1____ No chance
2____ Very unlikely
3____ Unlikely
4____ Likely
5____ Very Likely
6____ Certain to happen

A9. On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is your chance of getting breast cancer within the next 5 years?

_____% (Write answer here)

A10. Compared to other women your age and race, your chance of getting breast cancer in the next 5 years is….

1____ Much below average
2____ Below average
3____ Same average risk as women your age and race
4____ Above average
5____ Much above average

A11. What do you think is your chance of getting breast cancer in your lifetime? Please place a checkmark (√) or (X7) next to your answer.

1____ No chance
2____ Very unlikely

3____ Unlikely
4____ Likely
5____ Very Likely
6____ Certain to happen

A12. On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is your chance of getting breast cancer in your lifetime?

_____% (Write answer here)

A13. Compared to other women your age and race, your chance of getting breast cancer in your lifetime is….

1____ Much below average
2____ Below average
3____ Same average risk as women your age and race
4____ Above average
5____ Much above average

A14. Now think of 100 women your age, sex and race who are identical to you in all ways. Hence, their chance of getting breast cancer is exactly the same as yours. Out of these 100 women, how many do you think will get breast cancer during the next five years?

_____ (Write answer here)

A15. Out of these 100 women, how many do you think will get breast cancer during their lifetime?

_____ (Write answer here)

A16. Now think of 10,000 women your age and race who are identical to you in all ways. Hence, their chance of getting breast cancer is exactly the same as yours. Out of these 10,000 women, how many do you think will get breast cancer during the next five years?

_____ (Write answer here)

A17. Out of these 10,000 women, how many do you think will get breast cancer during their lifetime?

_____ (Write answer here)

A18. How **worried** are you about getting breast cancer in the next 5 years?

1____ Not at all worried
2____ Slightly worried
3____ Somewhat worried
4____ Very worried
5____ Extremely worried

A19. How **worried** are you about getting breast cancer in your lifetime?

1____ Not at all worried
2____ Slightly worried
3____ Somewhat worried
4____ Very worried
5____ Extremely worried

A20. How **fearful** are you about getting breast cancer in the next 5 years?

1____ Not at all fearful
2____ Slightly fearful
3____ Somewhat fearful
4____ Very fearful
5____ Extremely fearful

A21. How **fearful** are you about getting breast cancer in your lifetime?

1____ Not at all fearful
2____ Slightly fearful
3____ Somewhat fearful
4____ Very fearful
5____ Extremely fearful

Section B

Instructions: The next few questions are about Tamoxifen and breast cancer risk.

B1. The Food and Drug Administration has approved the use of Tamoxifen to prevent breast cancer among women who meet at least a certain minimal level of invasive breast cancer risk during a five year period. What is this minimum level of risk before a woman can consider taking Tamoxifen to prevent breast cancer? Give the precise value.

____ % risk of invasive breast cancer over the next five years.

____ # out of 10,000 over the next five years.

B2. In your opinion, women who meet the minimal level of invasive breast cancer risk based on the Food and Drug Administration's standards, have a risk of getting invasive breast cancer that is… (Please circle a response from 1 to 7).

Extremely Low	1	2	3	4	5	6	7	Extremely High

B3. Does your level of invasive breast cancer risk over the next five years, based on the Food and Drug Administration's standards, qualify you to take Tamoxifen? Note, this question

does not ask whether you should take Tamoxifen, but whether your level of invasive breast cancer over the next five years meets, if not exceeds, the Food and Drug Administration's minimal level of risk.

1___ Yes **(If yes, answer questions B11 to B17 only)**

5___ No **(If no, only answer questions B4 to B10 only)**

8___ Don't Know

Below FDA Criterion to Consider Tamoxifen

B4. How worried are you that your level of invasive breast cancer risk during the next five years was below the minimal level of risk based on the Food and Drug Administration's standards? Would you say you are…. (Please circle a response from 1 to 7).

Not at All Worried	1	2	3	4	5	6	7	Extremely Worried

B5. How anxious are you that your level of invasive breast cancer risk during the next five years was below the minimal level of risk based on the Food and Drug Administration's standards? Would you say you are…. (Please circle a response from 1 to 7).

Not at All Anxious	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Extremely** Anxious

B6. How fearful are you that your level of invasive breast cancer risk during the next five years was below the minimal level of risk based on the Food and Drug Administration's standards? Would you say you are…. (Please circle a response from 1 to 7).

Not at All Fearful	1	2	3	4	5	6	7	Extremely Fearful

B7. Given that you think your risk of invasive breast cancer was below the FDA standard, would you say your risk of breast cancer is… (Please circle a response from 1 to 7).

Extremely Low	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Extremely** High

B8. Out of 10,000 women your age and race who are identical to you In all ways, including having the exact same five year risk of breast cancer that you do, what percent of them would not qualify to take Tamoxifen?

____ % (Write answer here)

B9. Out of 10,000 women your age and race who are identical to you In all ways, including having the exact same five year risk of breast cancer that you do, how many of them would not qualify to take Tamoxifen?

____ out of 10,000 (Write answer here)

B10. We are about to show you information about the health risks and benefits of taking Tamoxifen for five years to prevent breast cancer. How interested are you in reviewing this information?

1____ Not at all interested

2____ Slightly interested

3____ Somewhat interested

4____ Very Interested

5____ Extremely interested

At or Above FDA Criterion to Consider Tamoxifen

B11. How worried are you that your level of invasive breast cancer risk during the next five years was at or above the minimal level of risk based on the Food and Drug Administration's standards? Would you say you are… (Please circle a response from 1 to 7).

Not at All Worried	1	2	3	4	5	6	7	Extremely Worried

B12. How anxious are you that your level of invasive breast cancer risk during the next five years was at or above the minimal level of risk based on the Food and Drug Administration's standards? Would you say you are… (Please circle a response from 1 to 7).

Not at All Anxious	1	2	3	4	5	6	7	Extremely Anxious

B13. How fearful are you that your level of invasive breast cancer risk during the next five years was at or above the minimal level of risk based on the Food and Drug Administration's standards? Would you say you are…(Please circle a response from 1 to 7).

Not at All Fearful	1	2	3	4	5	6	7	Extremely Fearful

B14. Given that you think your risk of invasive breast cancer was at or above the FDA standard, would you say your risk of breast cancer is…(Please circle a response from 1 to 7).

Extremely Low	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**Extremely** High

B15. Out of 10,000 women your age and race who are identical to you In all ways, including having the exact same five year risk of breast cancer that you do, what percent of them would qualify to take Tamoxifen?

____ % (Write answer here)

B16. Out of 10,000 women your age and race who are identical to you In all ways, including having the exact same five year risk of breast cancer that you do, how many of them would qualify to take Tamoxifen?

____ out of 10,000 (Write answer here)

B17. We are about to show you information about the health risks and benefits of taking Tamoxifen for five years to prevent breast cancer. How interested are you in reviewing this information?

1____ Not at all interested

2____ Slightly interested

3____ Somewhat interested

4____ Very Interested

5____ Extremely interested

Study ID#: _____

Appendix D.6.5

Page 1

We are going to ask you to rate your THOUGHTS and FEELINGS using two statements. Your thoughts and feelings may go together, or they might be different (you think one thing but feel another).

Press the spacebar for more instructions.

Page 2

Please respond as quickly and as accurately as possible to the statements that will appear on the screen. We will first ask your THOUGHTS. We will then ask your FEELINGS using the same statements.

Please keep your fingers on the '1' and '3' keys on the number pad throughout this task to select the statement that best reflects your thoughts or feelings.

Press the spacebar to start.

Page 3

Go ahead and position your fingers over the '1' and '3' keys on the number pad.

We'll start with an example of your THOUGHTS and FEELINGS about speeding.

Press the spacebar when ready.

Page 4

Now, please consider your THOUGHTS (what's in your mind) about speeding.

Press the spacebar when ready.

Page 5

What are your
THOUGHTS
about
speeding?

It's wise. (press 1)

It's unwise. (press 3)

Page 6

What are your
THOUGHTS
about
speeding?

I like it. (press 1)

I dislike it. (press 3)

Page 7

Now, please consider your FEELINGS (what's in your heart) about speeding.

Press the spacebar when ready.

Page 8

What are your
FEELINGS
about
speeding?

It's bad. (press 1)

It's good. (press 3)

Page 9

What are your
FEELINGS
about
speeding?

It's unwise. (press 1)

It's wise. (press 3)

Page 10

Now we'll begin asking your THOUGHTS and FEELINGS about your breast cancer risk estimate.

Go ahead and position your fingers over the '1' and '3' keys on the number pad.

Press the spacebar when ready.

Page 11

Now, please consider your THOUGHTS (what's in your mind?) about your breast cancer risk estimate.

Press the spacebar when ready.

Pages 12-20

What are your THOUGHTS about your breast cancer risk estimate?

I'm comfortable. (press 1)	I'm not comfortable. (press 3)
I'm not excited. (press 1)	I'm excited. (press 3)
I'm not in favor of it. (press 1)	I'm in favor of it. (press 3)
I'm against it. (press 1)	I'm for it. (press 3)
I like it. (press 1)	I dislike it. (press 3)
It's wonderful. (press 1)	It's terrible. (press 3)

It's pleasant.	It's unpleasant.
(press 1)	(press 3)

I'm calm.	I'm nervous.
(press 1)	(press 3)

It's bad.	It's good.
(press 1)	(press 3)

Page 21

Now, please consider your FEELINGS (what's in your heart?) about your breast cancer risk estimate.

Press the spacebar when ready.

Page 22-30

What are your FEELINGS about your breast cancer risk estimate?

It's bad.	It's good.
(press 1)	(press 3)

I'm not excited. (press 1)	I'm excited. (press 3)
It's unpleasant. (press 1)	It's pleasant. (press 3)
I'm against it. (press 1)	I'm for it. (press 3)
I like it. (press 1)	I dislike it. (press 3)
I'm not comfortable. (press 1)	I'm comfortable. (press 3)
I'm nervous. (press 1)	I'm calm. (press 3)
I'm not in favor of it. (press 1)	I'm in favor of it. (press 3)

It's wonderful.

(press 1)

It's terrible.

(press 3)

Page 31 and Page 53

Thank you!

Please let the interviewer know that you are ready to proceed to the next part of the study.

Page 32

We are again going to ask you to rate your THOUGHTS and FEELINGS using two statements. This time we'll be asking you about your thoughts and feelings about taking tamoxifen.

Press the spacebar for more instructions.

Page 33

Now, please consider your THOUGHTS (what's in your mind?) about your taking tamoxifen.

Press the spacebar when ready.

Page 34-42

What are your THOUGHTS about taking tamoxifen?

It's useful.

(press 1)

It's useless.

(press 3)

I'm for it.	I'm against it.
(press 1)	(press 3)
It's valuable.	It's worthless.
(press 1)	(press 3)
It's unimportant.	It's important.
(press 1)	(press 3)
I like it.	I dislike it.
(press 1)	(press 3)
It's unwise.	It's wise.
(press 1)	(press 3)
It's good.	It's bad.
(press 1)	(press 3)
I'm in favor of it.	I'm not in favor of it.
(press 1)	(press 3)

It's expensive. (press 1)	It's cheap. (press 3)

Page 43

Now, please consider your FEELINGS (what's in your heart?) about your taking tamoxifen.

Press the spacebar when ready.

Page 44-52

What are your FEELINGS about taking tamoxifen?

It's wise. (press 1)	It's unwise. (press 3)
It's useless. (press 1)	It's useful. (press 3)
It's bad. (press 1)	It's good. (press 3)

It's unimportant. (press 1)	It's important. (press 3)
It's worthless. (press 1)	It's valuable. (press 3)
I dislike it. (press 1)	I like it. (press 3)
It's cheap. (press 1)	It's expensive. (press 3)
I'm not in favor of it. (press 1)	I'm in favor of it. (press 3)
I'm for it. (press 1)	I'm against it. (press 3)

Study ID#: _____

Appendix D.6.6

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

Reactions to Tamoxifen Information -Frequency

Section A

Instructions: Please answer the following questions about the information you read on Tamoxifen.

A1. In your opinion, how <u>accurate</u> is the information presented to you about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all accurate and 6 is completely accurate.

Not at all accurate 0 1 2 3 4 5 6 Completely accurate

A2. In your opinion, how <u>credible</u>, that is believable, is the information presented to you about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all credible and 6 is completely credible.

Not at all credible 0 1 2 3 4 5 6 Completely credible

A3. In your opinion, how <u>trustworthy</u> is the information about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all trustworthy, and 6 is completely trustworthy.

Not at all trustworthy 0 1 2 3 4 5 6 Completely Trustworthy

A4. How <u>useful</u> was the information about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all useful and 6 is extremely useful.

Not at all useful 0 1 2 3 4 5 6 Extremely useful

A5. How understandable was the information about the health risks and benefits of taking Tamoxifen?

Circle a number between 0 and 6 where 0 is not at all understandable and 6 is completely understandable.

Not at all Understandable	0	1	2	3	4	5	6	Completely Understandable

A6. Overall, you found the information about Tamoxifen to be:

a)	Insignificant	0	1	2	3	4	5	6 Significant
b)	Unimportant	0	1	2	3	4	5	6 Important
c)	Of no Concern	0	1	2	3	4	5	6 Of much Concern
d)	Means Nothing	0	1	2	3	4	5	6 Means a lot
e)	Irrelevant	0	1	2	3	4	5	6 Relevant
f)	Does Not Matter to Me	0	1	2	3	4	5	6 Does Matter To Me

Section B

Instructions: For the next questions, assume that you were thinking about taking Tamoxifen for a period of five years. We want to know by how much you feel Tamoxifen would increase or decrease **your risk** for the specific event indicated. (1) Please place a checkmark (√) or (x) next to the answer that best describes if you feel that taking Tamoxifen will a) increase, b) decrease or c) would not affect your risk for that event. If you feel that taking Tamoxifen will increase or decrease your risk for that event, please indicate with a checkmark (√) or (x) if it increases or decreases it either very little, little, moderate amount, a lot or a great deal. If you feel taking Tamoxifen

would not affect your risk, put a checkmark by, “would not affect my risk.” You may refer to the handout we gave you from the website on Tamoxifen’s risks and benefits.

B1. **Invasive breast cancer**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B1a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B2. **Hip Fractures**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B2a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B3. **Endometrial Cancer**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B3a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B4. **Stroke**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B4a.) By how much would the risk ***increase/decrease***?
___Very little
___Little

___Moderate amount
___A lot
___A great deal

B5. **Pulmonary Embolism**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B5a.) By how much would the risk ***increase/decrease***?

___Very little
___Little
___Moderate amount
___A lot
___A great deal

B6. **In Situ breast cancer**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B6a.) By how much would the risk ***increase/decrease***?

___Very little
___Little
___Moderate amount
___A lot
___A great deal

B7. **Deep Vein Thrombosis**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B7a.) By how much would the risk ***increase/decrease***?

___Very little
___Little
___Moderate amount
___A lot
___A great deal

B8. **Colles' Fractures**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B8a.) By how much would the risk ***increase/decrease***?

___Very little

___Little
___Moderate amount
___A lot
___A great deal

B9. **Spine Fractures**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B9a.) By how much would the risk ***increase/decrease***?

___Very little
___Little
___Moderate amount
___A lot
___A great deal

B10. **Cataracts**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B10a.) By how much would the risk ***increase/decrease***?

___Very little
___Little
___Moderate amount
___A lot
___A great deal

Section C: You may refer to the handout we gave you from the website on Tamoxifen's risks and benefits.

Invasive breast cancer

C1a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how many do you think will get **invasive breast cancer** if they take tamoxifen for five years?
_____ out of 10,000

C1b.) Based on the information on the website, how many of these women do you think will get **invasive breast cancer** if they do not take tamoxifen for five years?
_____ out of 10,000

Hip Fractures

C2a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how

many do you think will have a **hip fracture** if they take tamoxifen for five years?
_____ out of 10,000

C2b.) Based on the information on the website, how many of these women do you think will have a **hip fracture** if they do not take tamoxifen for five years?
_____ out of 10,000

Endometrial Cancer

C3a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how many do you think will get **endometrial cancer** if they take tamoxifen for five years?
_____ out of 10,000

C3b.) Based on the information on the website, how many of these women do you think will get **endometrial cancer** if they do not take tamoxifen for five years?
_____ out of 10,000

Stroke

C4a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how many do you think will have a **stroke** if they take tamoxifen for five years?
_____ out of 10,000

C4b.) Based on the information on the website, how many of these women do you think will have a **stroke** if they do not take tamoxifen for five years?
_____ out of 10,000

Pulmonary Embolism

C5a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how many do you think will have a **pulmonary embolism** if they take tamoxifen for five years?
_____ out of 10,000

C5b.) Based on the information on the website, how many of these women do you think will have a **pulmonary embolism** if they do not take tamoxifen for five years?
_____ out of 10,000

In Situ breast cancer

C6a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how

many do you think will get **in situ breast cancer** if they take tamoxifen for five years?
_____ out of 10,000

C6b.) Based on the information on the website, how many of these women do you think will get **in situ breast cancer** if they do not take tamoxifen for five years?
_____ out of 10,000

Deep Vein Thrombosis

C7a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how many do you think will develop **deep vein thrombosis** if they take tamoxifen for five years?
_____ out of 10,000

C7b.) Based on the information on the website, how many of these women do you think will develop **deep vein thrombosis** if they do not take tamoxifen for five years?
_____ out of 10,000

Colles' Fractures

C8a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how many do you think will get a **Colles' fracture** if they take tamoxifen for five years?
_____ out of 10,000

C8b.) Based on the information on the website, how many of these women do you think will get a **Colles' fracture** if they do not take tamoxifen for five years?
_____ out of 10,000

Spine Fractures

C9a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how many do you think will develop a **spine fracture** if they take tamoxifen for five years?
_____ out of 10,000

C9b.) Based on the information on the website, how many of these women do you think will develop a **spine fracture** if they do not take tamoxifen for five years?
_____ out of 10,000

Cataracts

B10b.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, out of these 10,000 women, how

many do you think will develop **cataracts** if they take tamoxifen for five years?
_____ out of 10,000

B10c.) Based on the information on the website, how many of these women do you think will develop **cataracts** if they do not take tamoxifen for five years? _____ out of 10,000

Section D.

Instructions: Please answer the following questions based on the information you read about Tamoxifen. Place a checkmark (√) or (x) next to your answer.

D1. How interested are you in talking to a health care provider about taking Tamoxifen?

1___Not at all interested
2___Slightly interested
3___Somewhat interested
4___Very Interested
5___Extremely interested

D2. How motivated are you to talk to a health care provider about taking Tamoxifen?

1___Not at all motivated
2___Slightly motivated
3___Somewhat motivated
4___Very motivated
5___Extremely motivated

D3. How interested are you in taking Tamoxifen?

1___Not at all interested
2___Slightly interested
3___Somewhat interested
4___Very Interested
5___Extremely interested

D4. Overall, you have conflicting thoughts about taking Tamoxifen.

1___Strongly disagree
2___ Disagree
3___Agree
4___ Strongly agree

D5. Overall, you have mixed feelings about taking Tamoxifen.

1___Strongly disagree
2___ Disagree
3___Agree
4___ Strongly agree

D6. Overall, you are torn between taking and not taking Tamoxifen.

1___Strongly disagree
2___ Disagree
3___Agree
4___ Strongly agree

D7. For the next question, think about the overall benefits and risks related to taking Tamoxifen for a period of five years for a woman your age and race. Overall, you think …

1___ the benefits outweigh the risks by a lot
2___ the benefits outweigh the risks by a little
3___ the benefits and risks cancel each other out
4___ the risks outweigh the benefits by a little
5___ the risks outweigh the benefits by a lot

D8. For the next question, think about the overall benefits and risks related to taking Tamoxifen for a period of five years as they apply to **you** only. Overall, if you were to take Tamoxifen for five years, the …

1___ the benefits outweigh the risks by a lot
2___ the benefits outweigh the risks by a little
3___ the benefits and risks cancel each other out
4___ the risks outweigh the benefits by a little
5___ the risks outweigh the benefits by a lot

D9. How confident are you that you can now make a decision about whether taking Tamoxifen is right for you?

1___ Not at all confident
2___ Slightly confident
3___ Somewhat confident
4___ Very Confident
5___ Extremely confident

D10. Overall, do you think you have enough information to decide whether taking Tamoxifen is right for you?

___ Yes

___ No (In the space below please specify what more information you would need to make the decision whether Tamoxifen is right for you).

_____

D11. Would you take Tamoxifen monthly if it was free?

___ Yes
___ No
___ Don't know

D12. How much would you be willing to pay monthly, out of pocket, to take Tamoxifen?

$_____ /month

D13. In the space below, please tell us what information you read that stood out the most in terms of why

you **would want** to take Tamoxifen.

_____

D14. In the space below, please tell us what information you read that stood out the most in terms of why

you **would not want** to take Tamoxifen.

_____

D15. Based on the GYN clinical appointment schedule, you are due to see your gynecologist within the

next three months. Do you still plan to keep this appointment?

____Yes

____No

D16. During your visit to your gynecologist, how likely are you talk to him/her about taking Tamoxifen to prevent breast cancer? Please circle a number from 1-7 where 1 is definitely will not talk about tamoxifen and 7 is definitely will talk about tamoxifen.

.

Definitely	1	2	3	4	5	6	7	Definitely
Will **not** talk About Tamoxifen about Tamoxifen								**Will** talk

D17. Please tell us how strongly you agree or disagree with the following statement. As a woman's breast cancer risk goes up, the benefits of taking tamoxifen to prevent breast cancer outweight the risks. Do you...

Strongly disagree	1	2	3	4	5	6	7	Strongly agree

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

Reactions to Tamoxifen Information -Percentage

Section A

Instructions: Please answer the following questions about the information you read on Tamoxifen.

A7. In your opinion, how accurate is the information presented to you about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all accurate and 6 is completely accurate.

Not at all accurate	0	1	2	3	4	5	6	Completely accurate

A8. In your opinion, how credible, that is believable, is the information presented to you about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all credible and 6 is completely credible.

Not at all credible 0 1 2 3 4 5 6 Completely credible

A9. In your opinion, how trustworthy is the information about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all trustworthy, and 6 is completely trustworthy.

Not at all trustworthy 0 1 2 3 4 5 6 Completely Trustworthy

A10. How useful was the information about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all useful and 6 is extremely useful.

Not at all useful 0 1 2 3 4 5 6 Extremely useful

A11. How understandable was the information about the health risks and benefits of taking Tamoxifen? Circle a number between 0 and 6 where 0 is not at all understandable and 6 is completely understandable.

Not at all Understandable 0 1 2 3 4 5 6 Completely Understandable

A12. Overall, you found the information about Tamoxifen to be:

g) Insignificant 0 1 2 3 4 5 6 Significant

h) Unimportant 0 1 2 3 4 5 6 Important

i) Of no 0 1 2 3 4 5 6 Of much Concern Concern

j) Means 0 1 2 3 4 5 6 Means Nothing a lot

k) Irrelevant 0 1 2 3 4 5 6 Relevant

l) Does Not 0 1 2 3 4 5 6 Does Matter to Me Matter To Me

Section B

Instructions: For the next questions, assume that you were thinking about taking Tamoxifen for a period of five years. We want to know by how much you feel Tamoxifen would increase or decrease **your risk** for the specific event indicated. (1) Please place a checkmark (√) or (x) next to the answer that best describes if you feel that taking Tamoxifen will a) increase, b) decrease or c) would not affect your risk for that event. If you feel that taking Tamoxifen will increase or decrease your risk for that event, please indicate with a checkmark (√) or (x) if it increases or decreases it either very little, little, moderate amount, a lot or a great deal. If you feel taking Tamoxifen would not affect your risk, put a checkmark by, "would not affect my risk." You may refer to the handout we gave you from the website on Tamoxifen's risks and benefits.

B11. **Invasive breast cancer**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B1a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B12. **Hip Fractures**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B2a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B13. **Endometrial Cancer**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B3a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B14. **Stroke**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B4a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B15. **Pulmonary Embolism**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B5a.) By how much would the risk ***increase/decrease***?

___Very little
___Little
___Moderate amount
___A lot
___A great deal

B16. **In Situ breast cancer**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B6a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B17. **Deep Vein Thrombosis**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B7a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B18. **Colles' Fractures**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B8a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

B19. **Spine Fractures**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B9a.) By how much would the risk ***increase/decrease***?
___Very little

___Little
___Moderate amount
___A lot
___A great deal

B20. **Cataracts**

____ Increases my risk ____Decreases my risk ____ Would not affect my risk

B10a.) By how much would the risk ***increase/decrease***?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

Section C: You may refer to the handout we gave you from the website on Tamoxifen's risks and benefits.

Invasive breast cancer

C1a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent you think will get **invasive breast cancer** if they take tamoxifen for five years?
_____ %

C1b.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will get **invasive breast cancer** if they do not take tamoxifen for five years? _____ %

Hip Fractures

C2a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will have a **hip fracture** if they take tamoxifen for five years? _____ %

C2b.) Based on the information on the website, how on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will have a **hip fracture** if they do not take tamoxifen for five years? _____ %

Endometrial Cancer

C3a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will get **endometrial cancer** if they take tamoxifen for five years? _____ %

C3b.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will get **endometrial cancer** if they do not take tamoxifen for five years? _____ %

Stroke

C4a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will have a **stroke** if they take tamoxifen for five years? _____ %

C4b.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will have a **stroke** if they do not take tamoxifen for five years? _____ %

Pulmonary Embolism

C5a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will have a **pulmonary embolism** if they take tamoxifen for five years? _____ %

C5b.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will have a **pulmonary embolism** if they do not take tamoxifen for five years? _____ %

In Situ breast cancer

C6a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will get **in situ breast cancer** if they take tamoxifen for five years? _____ %

C6b.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will get **in situ breast cancer** if they do not take tamoxifen for five years? _____ %

Deep Vein Thrombosis

C7a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where

0%=no chance and 100%=certain to happen, what percent do you think will develop **deep vein thrombosis** if they take tamoxifen for five years? _____ %

C7b.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will develop **deep vein thrombosis** if they do not take tamoxifen for five years? _____ %

Colles' Fractures

C8a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will get a **Colles' fracture** if they take tamoxifen for five years?
_____ %

C8b.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent of these women do you think will get a **Colles' fracture** if they do not take tamoxifen for five years? _____ %

Spine Fractures

C9a.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will develop a **spine fracture** if they take tamoxifen for five years?
_____ %

C9b.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent of these women do you think will develop a **spine fracture** if they do not take tamoxifen for five years?
_____ %

Cataracts

B10b.) Now think of 10,000 women who are your age and race and who are identical to you in all ways. Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent do you think will develop **cataracts** if they take tamoxifen for five years? _____ %

B10c.) Based on the information on the website, on a scale from 0% to 100% where 0%=no chance and 100%=certain to happen, what percent of these women do you think will develop **cataracts** if they do not take tamoxifen for five years?
_____ %

Section D.

Instructions: Please answer the following questions based on the information you read about Tamoxifen. Place a checkmark (√) or (x) next to your answer.

D1. How interested are you in talking to a health care provider about taking Tamoxifen?

1___Not at all interested
2___Slightly interested
3___Somewhat interested
4___Very Interested
5___Extremely interested

D2. How motivated are you to talk to a health care provider about taking Tamoxifen?

1___Not at all motivated
2___Slightly motivated
3___Somewhat motivated
4___Very motivated
5___Extremely motivated

D3. How interested are you in taking Tamoxifen?

1___Not at all interested
2___Slightly interested
3___Somewhat interested
4___Very Interested
5___Extremely interested

D4. Overall, you have conflicting thoughts about taking Tamoxifen.

1___Strongly disagree
2___ Disagree
3___Agree
4___ Strongly agree

D5. Overall, you have mixed feelings about taking Tamoxifen.

1___Strongly disagree
2___ Disagree
3___Agree
4___ Strongly agree

D6. Overall, you are torn between taking and not taking Tamoxifen.

1___Strongly disagree
2___ Disagree
3___Agree
4___ Strongly agree

D7. For the next question, think about the overall benefits and risks related to taking Tamoxifen for a
period of five years for a woman your age and race. Overall, you think …

1___ the benefits outweigh the risks by a lot
2___ the benefits outweigh the risks by a little
3___ the benefits and risks cancel each other out
4___ the risks outweigh the benefits by a little
5___ the risks outweigh the benefits by a lot

D8. For the next question, think about the overall benefits and risks related to taking Tamoxifen for a period of five years as for as they apply to **you** only. Overall, if you were to take Tamoxifen for five years, the …

1___ the benefits outweigh the risks by a lot
2___ the benefits outweigh the risks by a little
3___ the benefits and risks cancel each other out
4___ the risks outweigh the benefits by a little
5___ the risks outweigh the benefits by a lot

D9. How confident are you that you can now make a decision about whether taking Tamoxifen is right for you?

1___ Not at all confident
2___ Slightly confident
3___ Somewhat confident
4___ Very Confident
5___ Extremely confident

D10. Overall, do you think you have enough information to decide whether taking Tamoxifen is right for you?

___ Yes

___ No (In the space below please specify what more information you would need to make the decision whether Tamoxifen is right for you).

_____

D11. Would you take Tamoxifen monthly if it was free?
___ Yes
___ No
___ Don't know

D12. How much would you be willing to pay monthly, out of pocket, to take Tamoxifen?

$_____ /month

D13. In the space below, please tell us what information you read that stood out the most in terms of why
you **would want** to take Tamoxifen.

_____

D14. In the space below, please tell us what information you read that stood out the most in terms of why
you **would not want** to take Tamoxifen.

_____

D15. Based on the GYN clinical appointment schedule, you are due to see your gynecologist within the next three months. Do you still plan to keep this appointment?

____Yes

____No

D16. During your visit to your gynecologist, how likely are you talk to him/her about taking Tamoxifen to prevent breast cancer? Please circle a number from 1-7 where 1 is definitely will not talk about tamoxifen and 7 is definitely will talk about tamoxifen.

.

Definitely Will **not** talk	1 Definitely	2	3	4	5	6	7 **Will** talk

D17. Please tell us how strongly you agree or disagree with the following statement. As a woman's breast cancer risk goes up, the benefits of taking tamoxifen to prevent breast cancer outweight the risks. Do you...

Strongly disagree	1	2	3	4	5	6	7	Strongly agree

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Appendix D.7

Lab Date: _____

Study ID#: _____
One-Month Follow-up Date: _____
Interviewer: _____
_____

The Effects of Informational Displays in Decisions about Tamoxifen use for Breast Cancer Chemoprevention

One-month Follow-up Questionnaire

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Hello, may I speak to _____. My name is _____ and I am calling from Duke University Medical Center. You recently helped us in a study on expressing your opinions about your breast cancer risk and about Tamoxifen to prevent breast cancer. I am calling you to see if this is a good time to do the last part of the study, which is a 15 minute survey asking you very similar questions as we did before about breast cancer and Tamoxifen. For your help, you will be sent $5.00. Would now be a good time to do this survey?

❑ No (but still interested)

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- **When would be a better day and/or time for someone to call you back?**

_____

(record call back date and time here)

- **Great, let me now get your contact information for our records.**
  - **Go to Caller Contact Sheet--record scheduled call back day and time.**

❑ No (no longer interested)

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Would you like to be considered for future studies?

❑ **Yes** **If yes, complete an "Interested in Future Studies" Form.**

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❑ No * Well, thank you for your time and have a nice day.

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❑ Yes

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Great! Let me start begin the survey.

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* Go to survey on next page.

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One-month Follow-up Questionnaire

Section A: Risk Perceptions

I will now ask your thoughts and feelings about getting breast cancer. For the first few questions, I will ask for your chances of getting breast cancer at different time frames.

A1. What do you think is your chance of getting breast cancer in the **next 5 years**, would you say…? (Read choices and place a checkmark (x) or (√) next to the respondent's answer.

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1____ No chance
2____ Very unlikely
3____ Unlikely
4____ Likely
5____ Very Likely
6____ Certain to happen
998____ DON'T KNOW
999____ REFUSED

A2. On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is **your** chance of getting breast cancer within the next 5 years?

_____ Put answer here
(**if they say 50**%, then ask ∗ **A2a) What do you mean by 50% chance? Would you say…..**

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1____ I am equally as likely to get or not get breast cancer
2____ I am at average risk
_____3____ Other?_____(explain _____)
998____ DON'T KNOW
999____ REFUSED

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998____ DON'T KNOW
999____ REFUSED

A3. Compared to other women your age and race, your chance of getting breast cancer in the next 5 years is….

1____ Much below average
2____ Below average
3____ Same average risk as women your age and race
4____ Above average
5____ Much above average
998____ DON'T KNOW
999____ REFUSED

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A4. What do you think is your chance of getting breast cancer **in your lifetime**, would you say…? (Read choices and place a checkmark (x) or (√) next to the respondent's answer.

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1____ No chance
2____ Very unlikely
3____ Unlikely
4____ Likely
5____ Very Likely
6____ Certain to happen
998____ DON'T KNOW
999____ REFUSED

A5. On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is **your** chance of getting breast cancer in your lifetime?

_____ Put answer here
(**if they say 50**%, then ask ∗ **A5a) What do you mean by 50% chance? Would you say…..**

1____ I am equally as likely to get or not get breast cancer
2____ I am at average risk
_____3____ Other?_____(explain _____)
998____ DON'T KNOW
999____ REFUSED

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Deleted: _____

998____ DON'T KNOW
999____ REFUSED

A6. Compared to other women your age and race, your chance of getting breast cancer in your lifetime is….

1____ Much below average
2____ Below average
3____ Same average risk as women your age and race
4____ Above average
5____ Much above average
998____ DON'T KNOW
999____ REFUSED

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14. Now think of 100 women your age, sex and race who are identical to you in all ways. Hence, their chance of getting breast cancer is exactly the same as yours. Out of these 100 women, how many do you think will get breast cancer during the next five years?

_____ Put answer here
998____ DON'T KNOW
999____ REFUSED

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15. Out of these 100 women, how many do you think will get breast cancer during their lifetime?

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_____ Put answer here
998____ DON'T KNOW
999____ REFUSED

16. How **worried** are you about getting breast cancer in the next 5 years? Would you say….

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1____ Not at all worried
2____ Slightly worried
3____ Somewhat worried
4____ Very worried
5____ Extremely worried
998____ DON'T KNOW
999____ REFUSED

17. How **worried** are you about getting breast cancer in your lifetime? Would you say….

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1____ Not at all worried
2____ Slightly worried
3____ Somewhat worried
4____ Very worried
5____ Extremely worried
998____ DON'T KNOW
999____ REFUSED

18. How **fearful** are you about getting breast cancer in the next 5 years? Would you say….

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1____ Not at all fearful
2____ Slightly fearful
3____ Somewhat fearful
4____ Very fearful
5____ Extremely fearful
998____ DON'T KNOW
999____ REFUSED

19. How **fearful** are you about getting breast cancer in your lifetime? Would you say….

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1____ Not at all fearful
2____ Slightly fearful
3____ Somewhat fearful
4____ Very fearful
5____ Extremely fearful
998____ DON'T KNOW
999____ REFUSED

Section B

Instructions: For the next questions, assume that you were thinking about taking Tamoxifen for a period of five years. We want to know by how much you feel Tamoxifen would increase or decrease **your risk** for the specific health events I will mention. If you feel that taking Tamoxifen will increase or decrease

Deleted: event indicated

your risk for that event, then we will ask you whether taking Tamoxifen increases or decrease the risk of that event by a very little, little, moderate amount, a lot or a great deal. If you feel taking Tamoxifen would not affect your risk for that event, please say, " it would not affect my risk."

EVENT

B21. **Invasive breast cancer - cancer cells that have spread to the surrounding tissue, lymph nodes, chest wall or distant sites in the body.** Would you say that taking tamoxifen….

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____ Increases your risk **B1a.)** By how much would the risk increase? Deleted: my
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B1b.)** By how much would the risk decrease? Deleted: my Deleted: B1a
___Very little
__Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk Deleted: my

B22. **Hip Fractures – cracking of the bones in or around the hip joint.** Would you say that taking tamoxifen….

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____ Increases your risk **B2a.)** By how much would the risk increase? Deleted: my
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B2b.)** By how much would the risk decrease? Deleted: my Deleted: B2a
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk Deleted: my

B23. **Endometrial Cancer – cancer of the inner lining of the uterus.** Would you say that taking tamoxifen….

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____ Increases your risk **B3a.)** By how much would the risk increase? Deleted: my
___Very little
___Little

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___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B3b.)** By how much would the risk decrease?

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Deleted: B3a

___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk

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B4. **Stroke – when a brain artery is ruptured or clogged.** Would you say that taking tamoxifen….

____ Increases your risk **B4a.)** By how much would the risk increase?

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___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B4b.)** By how much would the risk decrease?

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Deleted: B4a

___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk

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B5. **Pulmonary Embolism - a blood clot that gets lodged in the pulmonary artery and blocks blood flow to the lungs.** Would you say that taking tamoxifen….

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____ Increases your risk **B5a.)** By how much would the risk increase?

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___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B5b.)** By how much would the risk decrease?

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Deleted: B5a

___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk

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B6. **In Situ breast cancer, that is, non-invasive breast cancer, cancer cells that remain in the areas where they were found and have not invaded the surrounding tissue.** - Would you say that taking tamoxifen….

____ Increases your risk **B6a.)** By how much would the risk increase?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B6b.)** By how much would the risk decrease?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk

B7. **Deep Vein Thrombosis - blockage of the vein by a blood clot, usually under the calf muscles.** Would you say that taking tamoxifen….

____ Increases your risk **B7a.)** By how much would the risk increase?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B7b.)** By how much would the risk decrease?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk

B8. **Colles' Fractures – a fracture of the wrist.** Would you say that taking tamoxifen….

____ Increases your risk **B8a.)** By how much would the risk increase?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B8b.)** By how much would the risk decrease?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk

B9. **Spine Fractures -** **breakdown of bone tissue in the spine.** Would you say that taking tamoxifen….

____ Increases your risk **B9a.)** By how much would the risk increase?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B9b.)** By how much would the risk decrease?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk

B10. **Cataracts – clouding of the lens of the eye.** Would you say that taking tamoxifen….

____ Increases your risk **B10a.)** By how much would the risk increase?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Decreases your risk **B10b.)** By how much would the risk decrease?
___Very little
___Little
___Moderate amount
___A lot
___A great deal

____ Would not affect your risk

Section C
Instructions: I would now like to ask a few questions about whether you talked to others about taking Tamoxifen and some decisions you have reached about taking Tamoxifen?

C1. Since we last saw you on _____ (lab date), have you seen your gynecologist?

1___ Yes ☛ (go to question C2)
5___ No ☛ **C1a.** When will you see him/her? _____ ☛ (go to question C5)
998 DON'T KNOW
999 REFUSED
998____ DON'T KNOW
999____ REFUSED

C2. Did you talk to your gynecologist about taking Tamoxifen?
1___ Yes ☛ **C2a.** Did you initiate the discussion?
1___Yes ☛ (go to question C3)
5____No ☛ (go to question C3)
998____ DON'T KNOW
999____ REFUSED
5___ No ☛ (go to question C5)
998____ DON'T KNOW
999____ REFUSED

C3. And what questions did you ask your gynecologist about Tamoxifen?

998____ DON'T KNOW
999____ REFUSED

C4. What decision did you and your gynecologist reach about taking Tamoxifen? Was it…

1____ Not to take Tamoxifen
2____ Take Tamoxifen
3____ Delay making any decision
4____ Get another opinion from another physician (e.g., referral)
5____ Other (specify _____)

998____ DON'T KNOW
999____ REFUSED

*****STOP*****

☛Go to question C10 and complete the remaining questions.

---------- For those who did NOT talk to or see a gynecologist----------
(i.e. answered "No" to question C2)

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C5. Since we last saw you on _____ (lab date), did you talk to anyone about taking Tamoxifen?

1___ Yes ☛ (go to question C6)
5___ No ☛ (go to question C8)
998____ DON'T KNOW
999____ REFUSED

C6. Who did you talk to? (Do not read answers. Mark all that are stated.)

1___Another healthcare provider ___☛(**C6a**. specify discipline:_____)
2___Family member _____☛(**C6b.** specify who:_____)
3___Friend(s) _____☛(**C6c.** how many:_____)
4___Other _____☛(**C6d**. specify: _____)

998____ DON'T KNOW
999____ REFUSED

C7. After talking to this person, what decision did you reach about taking Tamoxifen? Was it…

1____ not to take Tamoxifen
2____ to take Tamoxifen
3____ to delay making any decision
4____ to get another opinion from another physician (e.g., referral)
5____ other ☛ (**C7a**. specify: _____)

998 DON'T KNOW
999 REFUSED

*****STOP*****

☛ Go to Question C10 after participant answers C7.

-------- For those who did NOT talk to anyone about taking Tamoxifen---------
(i.e. answered "No" to question C5)

C8. How interested are you in talking to a health care provider about taking Tamoxifen? Would you say…

1___Not at all interested
2___Slightly interested
3___Somewhat interested
4___Very Interested
5___Extremely interested
998____ DON'T KNOW
999____ REFUSED

C9. How motivated are you to talk to a health care provider about taking Tamoxifen? Would you say….

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1___Not at all motivated
2___Slightly motivated
3___Somewhat motivated
4___Very motivated
5___Extremely motivated
998____ DON'T KNOW
999____ REFUSED

*****STOP*****

☛ **Go to C10 after participants answers C9**

C10. Since we last saw you on _____ (lab date), how much thought have you given to taking Tamoxifen, on a scale from 1 to 7 where 1=no thought at all and 7=a great deal of thought.

No thought At all 1 2 3 4 5 6 7 A great deal of thought

C11. Overall, how effective do you think Tamoxifen is at preventing breast cancer? Would you say…

1____ Not at all effective
2____ Slightly effective
3____ Somewhat effective
4____ Very effective
5____ Extremely effective
998____ DON'T KNOW
999____ REFUSED

C12. As with most drugs, there are some medical benefits and medical risks (e.g. side effects). For the next question, we want you to think about the overall benefits and risks related to taking Tamoxifen for a period of five years. We realize that you may not know all the benefits and risks, but we would like to know what you think. Overall, do you think that the…..

1___ Benefits outweigh the risks by a lot
2___ Benefits outweigh the risks by a little
3___ Benefits and risks cancel each other out
4___ Risks outweigh the benefits by a little
5___ Risks outweigh the benefits by a lot

998____ DON'T KNOW
999____ REFUSED

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C13. How interested are you in taking Tamoxifen? Would you say….

1___Not at all interested
2___Slightly interested
3___Somewhat interested
4___Very Interested
5___Extremely interested
998____ DON'T KNOW
999____ REFUSED

C14. How confident are you that you can now make a decision about whether taking Tamoxifen is right for you? Would you say….

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1___ Not at all confident
2___ Slightly confident
3___ Somewhat confident
4___ Very confident
5___ Extremely confident
998____ DON'T KNOW
999____ REFUSED

C15. Overall, do you think you have enough information to decide whether taking Tamoxifen is right for you?

1___ Yes
5___ No
998____ DON'T KNOW
999____ REFUSED

Closing

Those are all the questions I have for now. Thank you so much for taking the time to complete this interview and participate in our study. You will get a check in the mail for $5.00 in about 3-4 weeks. When the study is completed, we will send you a short summary of the results. Do you have any questions? Have a great day!

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Appendix D.8

2006 Protocol Summary

TITLE: The effects of information displays in decisions about Tamoxifen use for breast cancer chemoprevention.

IRB #: 3109-06-10R5ER

I. Purpose and Aims of the Study:

The purpose of this study is to test how the numerical format of conveying breast cancer (BC) risk and the risks and benefits of taking Tamoxifen as a chemopreventive agent individually and jointly affect women's intentions to use Tamoxifen and talk to a health care provider about its use. The specific aims are to test how conveying:

AIM1: breast cancer risk as a frequency (e.g., 10 out of 10,000) or probability (e.g., .1%) affects perceived BC risks and negative emotions (e.g., fear, worry) about getting BC, the extent of processing information about Tamoxifen's risks and benefits (i.e., how much time is spent reviewing data on Tamoxifen), and intentions to use and talk to a health care provider about Tamoxifen use.

AIM2: Tamoxifen's risks and benefits as frequencies or probabilities, individually and jointly interact with the BC risk format to affect women's weighing of the risks and benefits, intentions to use and talk with a health care provider about Tamoxifen use.

II. Background & significance:

Behavioral interventions have focused primarily on early detection rather than the prevention of breast cancer; this trend is changing rapidly as chemoprevention agents, such as Tamoxifen, receive more attention. The Breast Cancer Prevention Trial's findings of 49% and 50% relative risk reductions for invasive and non-invasive breast cancers, respectively, among women taking Tamoxifen versus a placebo, led the FDA in 1998 to approve the prophylactic use of Tamoxifen among women whose estimated five-year risk of invasive breast cancer is 1.66% or greater. It is estimated that 29 million women may qualify for Tamoxifen; hence helping women to make well-informed decisions about Tamoxifen is critical.

An important challenge is how to facilitate the review of Tamoxifen information among higher risk women who may benefit from its use. Whether a woman reviews information on Tamoxifen depends, in part, on how she interprets her BC risk. Paradoxical research findings show that while most women overestimate their probability of getting BC, they also often feel their risks are average to below average. Thus, informing a woman of her estimated BC risk, which may be high enough to warrant consideration of chemoprevention but lower than she had imagined, might make her less likely to consider Tamoxifen use. Because of the potential public health benefits, it is important for these higher risk women to at least consider Tamoxifen. We argue that a novel way of motivating a woman to review information on Tamoxifen, while improving perceived BC cancer risk accuracy, is to express her five-year invasive BC risk as a numerical frequency rather than, as is current practice, a probability (e.g., percent). Information about the likelihood of some adverse event appears more risky when conveyed as a frequency than as a probability.

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The second challenge is to understand how the format of conveying Tamoxifen's risks and benefits to affects women's (a) overall weighing of risks and benefits and (b) intentions use Tamoxifen. Frequencies have been proposed by Tamoxifen experts as the preferred modality for conveying risk/benefit information, and the manufacturer of Tamoxifen currently displays risks and benefits as frequencies rather than probabilities. There are two potential problems with this practice: (1) as stated previously, frequencies have been shown to make events appear more risky, and (2) in decision-making, people often weigh negative information more heavily than positive information. Therefore it is likely that women would attend more to, and weigh more heavily, Tamoxifen's risks than its benefits. As a consequence, giving information in the form of risk frequencies may actually deter rather than facilitate women's consideration of Tamoxifen. We test a novel motivational information-processing model arguing that the extent of attention paid to Tamoxifen's risks and benefits is moderated by whether BC risks are presented as frequencies or probabilities.

This research is significant for several reasons. Decision-making research has shown that preferences are often created at the time individuals are presented with information about choices, especially for novel decisions such as Tamoxifen use. Variations in information displays are likely to significantly affect how higher-risk women attend to and react to such data. Evaluating the effects of different formats, and understanding the psychosocial mechanisms through which they affect decision-making, will become increasingly important as more women consider Tamoxifen, other breast cancer chemopreventive agents (e.g., Raloxifen), and chemopreventive drugs for cancer more broadly.

III. Design & procedures (Overview):

The study has 4 steps. In Step 1, higher-risk women will be recruited primarily from Duke University Health System gynecology (GYN) clinics. We will also recruit from other area GYN and primary care clinics as needed. At this time we are recruiting from Duke affiliates Durham OB/GYN and Harris and Smith OB/GYN clinics. In Step 2, those who imply consent (i.e. return a mailed Breast Cancer Risk Assessment Survey) and meet eligibility requirements will be contacted via phone and read a verbal consent to complete the Tamoxifen Baseline Questionnaire. If we do not receive via mail the Breast Cancer Risk Assessment questionnaire within two weeks, a member of the research study will call the woman to see if she is interested in the study, review the study with her and answer any questions she may have regarding the research study (the DOD phone screener script). If the woman is interested at that time, we will complete the Breast cancer Risk Assessment questionnaire over the phone with her. In addition, if study personnel are unable to contact the woman via phone, we will mail her a reminder postcard regarding the research study. In Step 3, one to two weeks after completion of the Tamoxifen Baseline Questionnaire, women will be asked to come to the Duke Medical Center's Risk Communication Laboratory (RCL) where they will be randomized to one of four experimental conditions of a 2 (format of BC risk feedback: probability/frequency), x 2 (format of Tamoxifen's risk and benefit: probability/frequency) between-subjects factorial design. In Step 4, participants will complete a one-month post-GYN phone survey. Details are discussed below.

Step 1: Recruitment and Characteristics of Study Participants: Our goal for this three year project is to recruit 280 to 300 English-speaking GYN patients who are between the ages of 35-65 and have a five-year Gail-calculated invasive BC risk >1.66%. Pregnant women will be excluded as Tamoxifen is contraindicated for them. Women

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with (1) a prior diagnosis of invasive breast cancer or in situ breast cancer (DCIS or LCIS), (2) have previously taken tamoxifen clinically, and (3) who participated in the Study of Tamoxifen and Raloxifene (STAR) breast cancer prevention trial will also be excluded as their risks for breast cancer cannot be quantified using the Gail model. The sampling frame will be obtained from Duke's OB/GYN clinics and its affiliates. On average, 6,800 patients are seen each year; 1400 are new patients and meet our age eligibility criteria. 80-90% of patients keep their appointment. In our pilot study, 70% of GYN patients expressed interest in participating**.**

To obtain permission to recruit their patients, we will first meet with GYN physicians to provide a description of the study and its goals. After obtaining verbal permission, we will request that they provide their signature for scanning onto the physician letter. As we obtain physician signatures, we will proceed with identifying eligible patients through E-browser. This program is used by various Duke clinics to store and retrieve patient appointments throughout the Medical Center and its affiliate locations. By assessing E-browser, we will be able to locate potential participants scheduled for an upcoming GYN appointment. Women's ages can also be obtained from E-browser. This will allow us to better sample, and therefore, select more appropriately, our mailings to potentially eligible women. Letters will only be sent to patients whose health care providers have provided their signatures, and therefore, have given us permission to contact their patients. Having physicians' signatures beforehand will allow us to generate letters for several women at once across multiple physicians. With the exception of demographic information (address, phone, age, gender, scheduled appointment), medical records will not be reviewed through the E-browser program.

To assess eligibility and interest, a three-page questionnaire (**Breast Cancer Risk Assessment Survey**), cover letter describing the study (**Tamoxifen Recruitment Cover Letter**), and a self-addressed return stamped envelope will be sent to women between the ages of 35 and 65 three months prior to their GYN appointment. It is not necessary for a consent form to be included with these materials as participants' completion and return of the breast cancer risk assessment survey indicates an implied consent to be called.

The Breast Cancer Risk Assessment Survey will assess: 1) data to derive women's five-year risk of invasive BC based on the Gail model, 2) demographic profile (e.g., race, education), 3) interest in joining a decision-making research study on Tamoxifen (no/yes), and 4) plans to keep their appointment. Women will be asked to return the Breast Cancer Risk Assessment Survey within a week. If, within two weeks, the survey has not been returned by mail, the woman will be called and asked to complete the Breast Cancer Risk Assessment Survey over the telephone using a telephone script similar to the initial letter sent to the participant (see DOD Phone Screener Script). By choosing to send back the Breast Cancer Risk Assessment Survey or completing it over the telephone the participant is agreeing to implied consent to provide us with the information.

We assume 50% of patients will return the questionnaire after these procedures. In a pilot conducted during August and September, 2000, we interviewed 155 gynecology

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patients ages 35 to 70. Of these, 16% (n=23) had risk estimates high enough to warrant Tamoxifen consideration. Of these 23 patients, 70% expressed interest in participating in a decision-making study on Tamoxifen. We assume these percentages will apply to the larger sample. Among those interested, 80% are expected to come to the RCL prior to their clinic appointment. Recruitment of roughly 70% of 6800 patients will begin during month two of year 1. In years 2 and 3 (until month 6), we will contact only new patients (about 1400 new patients/year). Based on these figures, we expect about 280 to 300 to join the study, 10 to 20/month. This translates to about 70 women per experimental group. We expect a 10% loss to follow-up.

Step 2: Baseline Interview & Informed Consent: Women who qualify and express interest in participating will be called, read a verbal consent over the phone for the Tamoxifen Baseline Questionnaire. Once verbal consent is obtained then the women will be asked to complete a 15-20 minute Tamoxifen Baseline Questionnaire phone survey. This Tamoxifen Baseline questionnaire will assess: 1) perceptions of breast cancer risks and emotions, 2) knowledge about tamoxifen, 3) weighing tamoxifen risks and benefits, and 4) interest in using and talking to a healthcare provider about taking tamoxifen. The main outcomes and mediating variables are described below. All items will be measured at baseline and during the laboratory portion **(Reactions to Breast Cancer Feedback Questionnaire)**, with the exception of covariates, which will be measured at baseline only and numeracy, which will be assessed at the RCL. In our previous research, internal consistencies of these measures exceeded .70; one-month test-retest correlations were ≥.60. A written consent form for the study will be signed at the laboratory session, and a copy will be given to the study participant.

Main Outcomes & Mediating Variables

Interest in using and talking to a health care provider about Tamoxifen: General interest in Tamoxifen use will be assessed by "How interested are you in taking Tamoxifen?" Interest in talking to a health care provider will be the sum of two items: "How interested are you in talking to a health care provider about taking Tamoxifen?", "How motivated are you about talking to a health care provider about taking Tamoxifen?" All three items will be scored 0="not at all interested" to 6= "extremely interested."

***Weighing Tamoxifen's overall risks and benefits*:** This will be assessed in two ways. First, participants will respond to the statement: "As with most drugs, there are some medical benefits and medical risks (e.g., side effects). We want you to think about the overall benefits and risks related to taking Tamoxifen for a period of five years. We realize you may not know all the benefits and risks." On a five-point scale, the response option will range from: 0= "benefits outweigh the risks by a lot" to 4= "risks outweigh the benefits by a lot." Second, participants will rate the magnitude of the increased or decreased risks for each health event from 0="not at all" to 6 ="a great deal." The sum of all perceived risks will be subtracted from the sum of all perceived benefits. A positive score reflects a greater benefit-to-risk ratio. These measures will be assessed at each time point.

Processing information about Tamoxifen's risks and benefits: Participants will be asked how much time they have spent thinking about taking Tamoxifen. (0="never" to 6="all the time") – assessed at all time points. As a more sensitive measure of elaboration, and as the preferred

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outcome in information-processing studies, we will assess the actual time women spend reviewing specific information on Tamoxifen's risks and benefits, using a web-based program. (see 3B below).

Perceptions of breast cancer risk and emotions (mediator): All women will be asked their perceived five-year and lifetime risk of getting invasive BC (0= "certain not to happen" to 6 = "certain to happen"). All women will be asked how worried, anxious and fearful they are about getting BC in the next five years/lifetime (0= "not at all" to 6="extremely"). The three items will be summed to form an overall index of negative feelings about getting BC. Items will be assessed at all time points.

Comprehension of Tamoxifen's risks and benefits (mediator): Women will be asked to indicate, for each of the 10 health states related to Tamoxifen use (e.g., stroke, endometrial cancer, embolisms) whether Tamoxifen use generally "increases", "decreases" or "does not affect risks." Correct and incorrect answers will be scored as a 1 or 0, respectively.

Covariate that might influence decision-making: In addition to age, race, and education, covariates will consist of whether the woman has an intact uterus, menopausal status, exposure to media on Tamoxifen use and attitudes towards this information, hypercholesterlemia, whether someone they know has used Tamoxifen for chemoprevention, and if so, how the individuals responded to it, and if the woman has a family history of BC, how the relative (s) tolerated Tamoxifen as an adjunct to treatment.

Step 3: Lab Session: Participants will sign and be given a copy of a written consent for the study at the beginning of the lab session. They will then be administered a series of written and computerized questionnaires during the lab session. These steps are described below.

3A: Randomization: Participants will be randomized using a SAS generated randomization program to receive breast cancer risk information as either a percentage format (e.g., 2%) or a frequency (2 women out of 100). Likewise, they will be randomized to receive tamoxifen information either as a percentage or a frequency This will generate 4 categories of participants, those receiving percentages for both breast cancer risk and tamoxifen (P,P), those receiving frequencies for both (F,F), and those receiving a combination (P, F and F, P).

3C: Need for Cognition, Trait Meta Mood, BIS– These 3 written surveys will be administered together (along with the Numeracy Questionnaire) at the beginning of the laboratory session and should take approximately 10-15 minutes to complete. They may have relevance to how people process health information.

3D: Manipulating Format for Communicating Breast Cancer Risk: Participants will be seated in front of a web-based program to inform them, using the modified Gail algorithm, of their five-year risk of invasive BC. To accustom women to the web-based program, and due to individual differences in computer literacy and reading speed, all participants will receive a brief practice tutorial on how to navigate between screens. Women randomized to the percentage format condition will be told of their five-year risk as a probability (e.g., 2%) **(Breast Cancer Risk Feedback –Probability).** Women in the frequency format condition will be told of their risk as a frequency (e.g., a woman with a 2.0% Gail-calculated five-year risk will be told that, out of 10,000 women exactly like her, 200 would be

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expected to get invasive BC during the next five years) **(Breast Cancer Risk Feedback –Frequency).** Both groups will be told of the minimum risk needed to consider Tamoxifen in the format consistent with their Gail score format (e.g., 1.66%, or 166 women out of 10,000) **(FDA Eligibility Requirement to take Tamoxifen).** Ms. Epps, an experienced genetic counselor within the Duke Breast Cancer High Risk Clinic, who as part of her tasks not only discusses BC risks, but also conveys information about Tamoxifen for chemoprevention, will review all this information with each participant and answer any questions or concerns. After reviewing this information, women's comprehension will be assessed by asking them to repeat their BC risk and state whether it was below, at, or above the threshold to consider Tamoxifen. We will then assess their interest in reviewing information on Tamoxifen (0="not at all" to 6="extremely interested"). Participants will then use the computer to display data on Tamoxifens's risks and benefits.

3E: E-Prime Program: After reviewing information about breast cancer risk on the web-based survey, participants will be prompted to begin part 1 of 2 of the E-prime Program. The E-prime program is a combination of psychological software tools used to assess reaction time to specific information. In part 1, participants will be asked their thoughts and feelings about their breast cancer risk given word association options. This part of the program will take approximately 5-10 minutes to complete. Part 2 of the E-prime will ask participants about their thoughts and feelings about Tamoxifen and will take approximately 5-10 minutes to complete. They will complete Part 2 after viewing information about Tamoxifen on the web-based survey.

3F: Breast Cancer Risk Feedback Survey – This survey is part of the web-based program and should take approximately 10 minutes to complete. It assesses: 1) understanding of breast cancer risk, 2) emotions about breast cancer risks, 3) understanding of FDA eligibility requirements for taking tamoxifen, and 4) interest in risks and benefits of tamoxifen. The survey is followed immediately by descriptions of health events related to taking tamoxifen.

3G: Manipulating Format for Communicating Tamoxifen's Risks and Benefits. Ms. Epps will prompt the computer to display information on Tamoxifen's risks and benefits using the web-based program – this program will monitor and continuously store on-line information acquisition behaviors, such as specific information sought, the sequence of acquisition, and the amount of time spent examining each item. Data on Tamoxifen will then follow. Participants will select, using a mouse, various field options. The first field will be whether they wish to look at Tamoxifen's benefits or risks. Once a field is chosen, they will have the option to select the categories of life-threatening, severe, and other health events related to Tamoxifen. The health event(s) under each subheading will be displayed, and they will have an option to click on an event, one at a time. Once an event is selected, the screen will provide a description of the event and then prompt the participant to click to the next screen **(Description of Health States for Tamoxifen).** The next screen will display how often that event occurs

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with and without using Tamoxifen for five years, either as a probability (i.e., percentage) or as a frequency for women randomized to the probability and frequency conditions, respectively. As part of a summary statement, women also will be informed of the absolute change in likelihood of the event's occurrence in a format consistent with their experimental group (e.g., 50% less cases of BC, 200 fewer cases of BC) – (for a close facsimile of how these data will be displayed for each event (**Summary of Benefits and Risks Related to Tamoxifen Use- Frequency/ Percentage).** The risks and benefits for each health event will be tailored to a woman's age, race, BC risk, and whether she has a uterus – individual differences in the magnitude of the risks and benefits will be used as covariates in outcomes analyses. Participants will be able to review the data in any order and as often as they desire. After reviewing the data, we will assess using the computer, comprehension, weighing of the risks and benefits, and intentions to use and talk to a health care provider about Tamoxifen **(Reactions to Tamoxifen Information Questionnaire).**

3H: Reaction to Tamoxifen Information Survey – This 10 minute written survey assesses: 1) understanding of tamoxifen risks and benefits, and 2) interest and intent in talking to a healthcare provider about tamoxifen.

Step 4: **Follow-up survey**: As exploratory outcomes, women will be mailed a one-page survey one-month after their visit to see if they talked to their gynecologist or any other health care provider about Tamoxifen, and if so, what was discussed. We will also ask questions to assess their perceived BC risk and overall weighing of Tamoxifen's risks and benefits to see if the lab results are sustained **(One-Month Follow-up Survey).** This survey should take approximately 15 minutes to complete. Participants will be asked to mail back the survey in a self-addressed stamped envelope.

IV. Pilot-testing of the usability of computerized surveys:

We will pilot test, on the first 10 eligible participants entering the study, The **Evaluative Pilot Questionnaire for Usability of Computerized Surveys will be used to** assess the participants' understanding of the information, instructions and questions presented to them on the Web-Based survey and E-prime software program. Data collected from this questionnaire will be useful in determining clarity and understandability of the computer-based questionnaires for making any necessary revisions. These women will be recruited through the same channels and undergo the same procedures as the larger sample. The only exceptions are that they will complete the Evaluative Pilot Questionnaire for Usability of Computerized Surveys in addition to the other surveys.

V. Health Care Provider Training and Referrals. All health care providers (e.g. GYN and primary care physicians and nurse practioners) will get educational written information on Tamoxifen, prepared by Dr. Marcom, a BC clinical oncologist, and Principal Investigator

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at Duke Medical Center of the STAR trial comparing Tamoxifen and Raloxifen. It will be recommended that women who desire to take Tamoxifen after talking to their gynecologist be referred to Dr. Marcom, who can assess participants' individual risk factors, including extensive family and gynecologic history that are not fully captured in the study procedures.

VI. Hypotheses: The rationale for the predictions below is contained in a copy of the grant in section A.5. The specific hypotheses are:

HI: Women who receive BC risk information as a frequency rather than as a probability (i.e., percentage) will view their risks as higher and will express more negative affect (e.g., worries, fear) about getting BC.

H2: Greater perceived BC risks and negative affect will lead to a stronger motivation to learn about Tamoxifen and process information on Tamoxifen's risks and (especially) benefits.

H3: The format used to convey BC risk will interact with the format used to convey Tamoxifen's risk and benefits. Specifically, women who get BC risk feedback and data on Tamoxifen's risks and benefits as frequencies will report: 1) the highest benefit and least risk for taking Tamoxifen (i.e., highest benefit/risk ratio), and 2) the strongest intentions to use and talk to a health care provider about Tamoxifen.

VII. Data analysis & monitoring – Our power calculations are based on 280 women (n=70 per group) at an alpha of .01. We will use a 2-factor (format of conveying BC risk x format of conveying Tamoxifen's risks and benefits) repeated-measures ANOVA design controlling for the covariates stated in D.5/7, comparing baseline and RCL results. Hypotheses of interest will test the main effects of BC risk format, Tamoxifen format and the interaction of the two formats. Estimates of statistical power were aided by our pilot study (see A.6.of appendix A) that had several of the same measures proposed for this study. ANOVAs on the pre-post difference scores in our pilot yielded overall R^2 statistics between 4-9%. We assume conservative estimates that the overall R^2 in the proposed study will average 5%. Applying Cohen's methods to ANOVA designs, by subdividing the R^2 of 5% into portions attributable to the main effect of BC risk, the main effect of Tamoxifen risk, and their interaction, we have 80% power to detect an R^2 of 4.61%, – we can detect about 4.5% additional variance beyond the main effects. The BC risk feedback by Tamoxifen format interaction predicting the overall weighing of Tamoxifen's risk and benefits (see A.6 of Appendix A) -- our main interaction hypothesis -- produced an R^2 of 5% beyond the main effects; the main effects explained less than .5% of the R^2. We can readily detect such an interaction in the proposed study assuming similar effect sizes (see H3). Assuming a normal distribution, we can detect .363 (alpha =.05) or .411 (alpha=.01) of a standard deviation change in means between groups for main effects (see HI and H2). Mediational analyses predicting that format will affect: 1) information processing about Tamoxifen via perceived risks and emotions, and 2) intentions to use Tamoxifen and talk to a health care provider via the overall weighing of Tamoxifen's risks and benefits, will be tested use Baron and Kenny's approach (grant reference 40).

VIII. Data Storage and Confidentiality: All written information will be assigned numerical identification to retain the anonymity of participants and will be locked in the principal investigator's office. Only staff personnel with authorized computer passwords will have

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access to participants' responses. Here too, participants will be given a unique code number. The key to the code will be kept locked separately from the study records. The U.S. Army Medical Research and Material Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

IX: **Compensation and costs for participation:** All participants will get $40.00 for completing all aspects of the study, $5 for each of the telephone interviews and $30 for coming into the Risk Lab for the face-to-face interview. Participants will not incur any costs for participation.

X: **Risk/benefit assessment:** Women benefit in two main ways. They will learn about their breast cancer risks and what would be the perceived risks and benefits of taking Tamoxifen. In addition, for women who do pursue a consultation with Dr. Marcom and who have the medical profile where Tamoxifen is indicated, these women may ultimately benefit by taking the drug that may lower their breast cancer risk.

In general, we have found that women overestimate their breast cancer risks; therefore, we are more likely to find that women will be relieved to know their risk is lower than expected.

There are no physical risks from this study. Risks from participation in the study include 1) the potential for heightened anxiety and fear related to knowledge of breast cancer risk information or specific information about tamoxifen and 2) loss of confidentiality resulting in the potential for discrimination. Given the security controls on the study, the potential for loss of confidentiality is considered a low risk. Women experiencing any heightened anxiety or fear can ask to speak with Dr. Lipkus about any concerns they have in interpreting the breast and Tamoxifen information during the debriefing session. They will also have the chance to talk to their gynecologist and Dr. Marcom with any further medical questions.

XI: **Process for Protocol Modifications:** Any modifications, extensions of, departures from or termination from the existing protocol (i.e. amendments) will be submitted in writing to the local IRB for review and approval, using a standard form. After local IRB approval, the amendment will be submitted to the HSRRB for review and approval.

XII: **Process for Reporting of Adverse Events:** Unanticipated problems involving risks to subjects or others, serious adverse events related to participation in the study and all subject deaths will be reported to the local IRB using a standard reporting form. They will also be promptly reported by phone (301-619-2165), by mail (hsrrb@det.amedd.army.mil), or by facsimile (301-619-7803) to the Army Surgeon General's Human Subjects Research Review Board (HSRRB). A complete written report, follow the initial telephone call, will be sent to the U.S. Army Medical Research and Materiel Command, ATTN:MCMR-ZB-QH, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

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Appendix E

NAME/HIGHEST DEGREE	DEPT.	STUDY ROLE	EMAIL ADDRESS
2007 renewal			
Isaac Lipkus, PhD	Psychiatry	Study PI	Lipku001@mc.duke.edu
Shelly Epps, MS	Cancer Control	Study Coordinator/ Genetics Counselor	Clark086@mc.duke.edu
Alaatin Erkanli, PhD		Statistician	
2006 Renewal			
Isaac Lipkus, PhD	Psychiatry	Study PI	Lipku001@mc.duke.edu
Shelly Epps, MS	Cancer Control	Study Coordinator/ Genetics Counselor	Clark086@mc.duke.edu
2005 Renewal			
Isaac Lipkus, PhD		Study PI	Lipku001@mc.duke.edu
Lisa Werner, MA Ed.		Study Coordinator	Werne006@mc.duke.edu
Meg Weems		Project Coordinator	Weems002@mc.duke.edu
Shelly Epps, MS		Genetics Counselor	Clark086@mc.duke.edu
Teresa Marshall, MS		Data Technician	Marsh067@mc.duke.edu
2004 Renewal			
Isaac Lipkus, PhD	Study PI	Lipku001@mc.duke.edu	
Lisa Werner, MA Ed.	Study Coordinator	Werne006@mc.duke.edu	
Shelly Epps, MS	Project Coordinator	Clark086@mc.duke.edu	
2003 and 2002 Renewals			
Isaac Lipkus, PhD	Study PI	Lipku001@mc.duke.edu	
Sonya G. Green, MPH	Clinical Research Coordinator		
2001 Submission			
Isaac Lipkus, PhD	Study PI	Lipku001@mc.duke.edu	
Deborah Iden, MPH	Clinical Research Coordinator		

Appendix F

TITLE: HIGHER RISK WOMEN'S BASIC UNDERSTANDING AND INTEREST IN TAMOXIFEN FOR BREAST CANCER CHEMOPREVENTION

AUTHORS: ISAAC LIPKUS, PAUL MARCOM, AND ELLEN PETERS

Affiliations: Duke University Medical Center and Oregon Decisional Research Institute

Tamoxifen has been approved by the FDA as a chemopreventive agent against breast cancer for women who have a five-year breast cancer risk of 1.66% or greater. To date, very little it known about how women who qualify for tamoxifen perceive the risks and benefits of its use as conveyed in different communication formats. As part of a larger ongoing trial, 38 women recruited from OB/GYN clinics in central North Carolina and who qualified for tamoxifen were provided with a computerized decision aid that tailored five health risks and five health benefits of taking tamoxifen for five years. This information was provided numerically in a frequency or percentage format. After reviewing the information, participants were asked: 1) whether tamoxifen increased, decreased or did not affect their chances of experiencing the 10 health events mentioned, 2) for their overall weighing of the risks and benefits for self (1=benefits outweigh the risks by a lot to 5=risks outweigh the benefits by a lot) as well as for others, 3) interest in taking tamoxifen (1=not at all to 5=extremely), and 4) motivation and interest in talking to a health care provider about tamoxifen (1=not at all to 5=extremely). All women completed a measure of numeracy.

Participants were able to identify on average 7 out of 10 events correctly as to whether tamoxifen increased or decreased their chances of experiencing the health events. Women with greater numeracy (M =8.3 out of 11) were more likely to specify correctly how tamoxifen affected their chances of experiencing these events ($r=.59$, $p<.0001$). The numerical format did not affect understanding of the direction of these risks and benefits, although it was slightly better in the frequency than percentage format (M=7.6 vs. 6.8). Participants viewed there being more risks than benefits of taking tamoxifen for themselves versus other women their age and race (M=2.89 vs. 3.22, $p<.0001$). Further, they expressed slight to moderate levels of motivation and interest in talking to a health care provider (Ms=2.4 and 2.5, respectively) and slight interest in taking tamoxifen (M=1.9). Interest in using tamoxifen was higher among women whose actual benefits outweigh the risks ($r=.41$, $p<.02$).

These very preliminary data suggest that higher risk women after being exposed to numerical information have a fair understanding of tamoxifen's risks and benefits, especially among those more numerate, although there is room for improvement. Further, many of these women expressed little interest in using tamoxifen viewing the risks outweighing the benefits. Women may need further prognostic indicators (e.g., findings of atypia, BRCA1/2 mutations) before modifying their beliefs and interests in using tamoxifen for chemoprevention.

DAMD17-03-1-0382

The gynecology clinics at Duke University Medical Center are trying to better educate women about their breast cancer risks, and especially, how to inform and help women make decisions about new medications that can help prevent breast cancer, especially Tamoxifen. We would like to ask you to be evaluated for a study assessing breast cancer risk and reviewing possible prevention options. If you have had a past diagnosis of breast cancer, this assessment will not be accurate for you. Therefore, you are not eligible to participate in this study. In this case, you may disregard this letter and we do apologize if it has been disturbing or upsetting to you in any way. If you are interested in learning more about the study, please continue reading this letter.

In recent years, a number of clinical studies have shown that Tamoxifen can lower breast cancer in women who may be at increased risk. Among these women, the decision to use Tamoxifen needs careful thought about the drug's risks and benefits. This study will look at ways to help women at possibly higher risk of breast cancer make decisions about Tamoxifen use. Women in the study are NOT being asked to take Tamoxifen. ***Please do not think you are at higher risk merely because you got this letter.***

The first step is to see if you qualify for this study by assessing your risk of breast cancer. By filling out the enclosed questionnaire, we can assess your breast cancer risk; this can help inform you whether considering medical therapy to lower your risk might be something to think about. This information will be kept confidential and will not become part of your medical record at the gynecology clinic unless you discuss it with your healthcare provider. Your healthcare provider will not be sent information about your participation in this study.

If your risk for breast cancer is such that you qualify for taking Tamoxifen, you will be asked to join the study. Remember, you are NOT being asked to take Tamoxifen to be part of this study. At that time, you will be asked to take part in a short phone survey lasting no more than 15 minutes. After the survey, you will be asked to come to Brightleaf Square in Durham where you will be shown your breast cancer risk estimate and information about the risks and benefits of Tamoxifen use, followed by some questions on the information. This should last no more than an hour. One month after your next scheduled gynecological visit, you will be called one more time for a short 10-minute survey. For your help in this study, you will be given $40.00.

We hope that you will complete the enclosed questionnaire and mail it back in the self-addressed stamped envelope. If we do not receive your questionnaire within the next week, a reminder post-card will be mailed to you. If we do not hear from you within a week after mailing you the post-card, a member of the study will call you to see if you are interested in the study, review the study with you and answer any questions you may have. If you are interested at that time, we will complete the questionnaire over the phone with you.

Through this study, we hope to improve how we provide important information to women regarding their health decisions. If you have further questions, they can be addressed to Dr. Isaac Lipkus, the principal investigator for the study, at 919-956-5644.

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❑ No **(☛ skip to question 5)**

❑ Other (You have an adopted sister/s) **(☛ skip to question 5)**

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❑ No **(☛ skip to question 6)**
❑ Other (You have an adopted daughter/s) **(☛ skip to question 6)**

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❑ Yes
❑ No
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- ❑ Yes
- ❑ No
- ❑ Don’t know

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❑ **Yes**
❑ **No**
❑ **Don't know**

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❑ No **(☛ skip to question 5)**

❑ Other (You have an adopted sister/s) **(☛ skip to question 5)**

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❑ No **(☛ skip to question 6)**
❑ Other (You have an adopted daughter/s) **(☛ skip to question 6)**

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❑ Yes
❑ No

❑ Don’t know

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❑ Yes
❑ No
❑ Don’t know

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❑ Yes
❑ No
❑ Don't know

Are you currently on hormone replacement therapy? ❑ Yes

Have you ever taken Tamoxifen (Nolvadex)?

Have you participated in the Breast Cancer Trial (BCPT) or the Study of Tamoxifen and Raloxifene (STAR) Trial?

Have you ever had a hysterectomy? (in other words, *uterus surgically removed?)*

❑ Yes
❑ No
❑ Don't know

11. Are you pregnant now?
❑ Yes
❑ No

12. What is your age? _____
(write age here)

13. What is your Date of Birth: _____ / _____/ _____
(Month) (Day) (4-digit year)

14. Which of the following best describes your race or ethnic background?

❑ White
❑ Hispanic
❑ Black
❑ Asian or Asian American
❑ Hawaiian, Native
❑ Native American
❑ Asian Indian
❑ Filipino
❑ Other (specify: _____)
❑ Don't know

15. What is your highest level of education?

❑ Some high school

❑ High school graduate

❑ Trade/technical/vocational school

❑ Some college

❑ College graduate

❑ Post graduate work/graduate degree

❑ Don't know

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16. Are you interested in joining a research study about helping women make informed decisions about whether taking Tamoxifen is right for them to prevent breast cancer? You will *NOT* be asked to take Tamoxifen.

❑ Yes ❑ No

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call you to tell you more about this study

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❑ **No** ☛ Ok, Would you like to be considered for future studies?

❑ Yes ☛ If yes, complete an “Interested in Future Studies” Form.

❑ No ☛ Well, thank you for your time and have a nice day.

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you general questions about your

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We will pay you $40.00 for your help. Do you have any questions? Does this sound like something you'd be interested in?

There are no physical risks associated with this stu

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There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this can not be guaranteed.

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You may skip survey questions that you do not want to answer.

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Now we're finally ready to start the survey!

BEGIN Baseline SURVEY

If not a good time to complete the survey: What is a good time for us to call you back?

If does not have time for survey now, record time and date of call back time and file. Then thank the subject and hang up.

Section Break (Next Page)

Baseline Questionnaire

Section A: Risk Perceptions

I will now ask your thoughts and feelings about getting breast cancer. For the first few questions, I will ask for your chances of getting breast cancer at different time frames.

1. What do you think is your chance of getting breast cancer in the **next 5 years**, would you say…? (Read choices and place a checkmark (x) or (√) next to the respondent's answer.

1____ No chance
2____ Very unlikely
3____ Unlikely
4____ Likely
5____ Very Likely
6____ Certain to happen
8____ DON'T KNOW
9____ REFUSED

On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is **your** chance of getting breast cancer within the next 5 years?

_____ Put answer here
(**if they say 50%**, then ask * 2b**) What do you mean by 50% chance? Would you say….**
1____ I am equally as likely to get or not get breast cancer
2____ I am at average risk
3____ Other? 2c) (explain _____)
8____ DON'T KNOW
9____ REFUSED

998____ DON'T KNOW
999____ REFUSED

3. Compared to other women your age and race, your chance of getting breast cancer in the next 5 years is….

1____ Much below average
2____ Below average
3____ Same average risk as women your age and race
4____ Above average
5____ Much above average
8____ DON'T KNOW
9____ REFUSED

Section Break (Next Page)

4. What do you think is your chance of getting breast cancer **in your lifetime**, would you say…? (Read choices and place a checkmark (x) or (√) next to the respondent's answer.

1____ No chance
2____ Very unlikely
3____ Unlikely
4____ Likely
5____ Very Likely
6____ Certain to happen
8____ DON'T KNOW
9____ REFUSED

5a. On a scale from 0% to 100% where 0%= no chance and 100%= certain to happen, what do you think is **your** chance of getting breast cancer in your lifetime?

_____ Put answer here
(**if they say 50%**, then ask * 5b**) What do you mean by 50% chance? Would you say….**

1____ I am equally as likely to get or not get breast cancer
2____ I am at average risk
3____ Other? 5c) (explain _____)
8____ DON'T KNOW
9____ REFUSED

998____ DON'T KNOW
999____ REFUSED

6. Compared to other women your age and race, your chance of getting breast cancer in your lifetime is….

1____ Much below average
2____ Below average
3____ Same average risk as women your age and race
4____ Above average
5____ Much above average
8____ DON'T KNOW
9____ REFUSED

Section Break (Next Page)

7. Now think of 100 women your age, sex and race who are identical to you in all ways. Hence, their chance of getting breast cancer is exactly the same as yours. Out of these 100 women, how many do you think will get breast cancer during the next five years?

_____ Put answer here
998____ DON'T KNOW
999____ REFUSED

8. Out of these 100 women, how many do you think will get breast cancer during their lifetime?

_____ Put answer here
998____ DON'T KNOW
999____ REFUSED

9. How **worried** are you about getting breast cancer in the next 5 years? Would you say….

1____ Not at all worried
2____ Slightly worried
3____ Somewhat worried
4____ Very worried
5____ Extremely worried
8____ DON'T KNOW
9____ REFUSED

10. How **worried** are you about getting breast cancer in your lifetime? Would you say….

1____ Not at all worried
2____ Slightly worried
3____ Somewhat worried
4____ Very worried
5____ Extremely worried
8____ DON'T KNOW
9____ REFUSED

11. How **fearful** are you about getting breast cancer in the next 5 years? Would you say….

1____ Not at all fearful
2____ Slightly fearful
3____ Somewhat fearful
4____ Very fearful
5____ Extremely fearful
8____ DON'T KNOW
9____ REFUSED

Section Break (Next Page)

How **fearful** are you about getting breast cancer in your lifetime? Would you say…

1____ Not at all fearful
2____ Slightly fearful
3____ Somewhat fearful
4____ Very fearful
5____ Extremely fearful
8____ DON'T KNOW
9____ REFUSED

As I mentioned, as part of this study you will be given information about your chance of getting
breast cancer. A woman can be informed of her breast cancer risk in different ways. Her risk can be communicated 1) ***verbally***, for example being told that she is at low, average or high risk, or 2) **numerically**, for example being told that her risk is 5%, 25%, 60% and so forth. If we were to inform you of your breast cancer risk, would you prefer it being communicated to you verbally, numerically, both verbally and numerically, or do you not have a preference?

1___ Verbally
2___ Numerically
3___ Prefer both verbally and numerically
4___ No preference
8____ DON'T KNOW
9____ REFUSED

Section B

Instructions: I would now like to ask a few questions about Tamoxifen, a drug that has been shown to reduce the risk of breast cancer.

Have you ever heard of Tamoxifen?

1___ Yes
5___ No
8____ DON'T KNOW
9____ REFUSED

Tamoxifen is used for the prevention or for the treatment of breast cancer. For the following question, only think of women who have **never** been treated for breast cancer. Have you ever known of someone who took Tamoxifen to prevent breast cancer?
1___ Yes
5___ No
8____ DON'T KNOW
9____ REFUSED

Section Break (Next Page)

Have you ever seen a TV commercial on using Tamoxifen to prevent breast cancer?
1___ Yes
5___ No
8____ DON'T KNOW
9____ REFUSED

Have you ever read an article on using Tamoxifen to prevent breast cancer?
1___ Yes
5___ No
8____ DON'T KNOW
9____ REFUSED

Have you ever heard about Tamoxifen on the radio?
1___ Yes
5___ No
8____ DON'T KNOW
9____ REFUSED

Have you ever heard about Tamoxifen from a friend?
1___ Yes
5___ No
8____ DON'T KNOW
9____ REFUSED

Overall, how effective do you think Tamoxifen is at preventing breast cancer? Would you say…

1____ Not at all effective
2____ Slightly effective
3____ Somewhat effective
4____ Very effective
5____ Extremely effective
8____ DON'T KNOW
9____ REFUSED

Section Break (Next Page)

As with most drugs, there are some medical benefits and medical risks (e.g. side effects). For the next question, we want you to think about the overall benefits and risks related to taking Tamoxifen for a period of five years. We realize that you may not know all the benefits and risks, but we would like to know what you think. Overall, do you think that the…..

1___ Benefits outweigh the risks by a lot
2___ Benefits outweigh the risks by a little
3___ Benefits and risks cancel each other out
4___ Risks outweigh the benefits by a little
5___ Risks outweigh the benefits by a lot

8____ DON'T KNOW
9____ REFUSED

According to the U.S. Food and Drug administration, Tamoxifen can only be given to women who have a high enough level of breast cancer risk. Do you think your level of breast cancer risk during the next five years is high enough to qualify you to take Tamoxifen to prevent breast cancer?

1___ Yes
5___ No
8____ DON'T KNOW
9____ REFUSED

How interested are you in talking to a health care provider about taking Tamoxifen? Would you say….

1___Not at all interested
2___Slightly interested
3___Somewhat interested
4___Very Interested
5___Extremely interested
8____ DON'T KNOW
9____ REFUSED

How motivated are you to talk to a health care provider about taking Tamoxifen? Would you say….

1___Not at all motivated
2___Slightly motivated
3___Somewhat motivated
4___Very motivated
5___Extremely motivated
8____ DON'T KNOW
9____ REFUSED

Section Break (Next Page)

If you were to consider taking Tamoxifen to prevent breast cancer, would you want the decision to be made….

1___ by your doctor
2___ by you
3___ equally between you and your doctor
8____ DON'T KNOW
9____ REFUSED

How interested are you in taking Tamoxifen? Would you say….

1___Not at all interested
2___Slightly interested
3___Somewhat interested
4___Very Interested
5___Extremely interested
8____ DON'T KNOW
9____ REFUSED

How confident are you that you can now make a decision about whether taking Tamoxifen is right for you? Would you say…..

1___ Not at all confident
2___ Slightly confident
3___ Somewhat confident
4___ Very confident
5___ Extremely confident
8____ DON'T KNOW
9____ REFUSED

Overall, do you think you have enough information to decide whether taking Tamoxifen is right for you?

1___ Yes
5___ No
8____ DON'T KNOW
9____ REFUSED

Section Break (Next Page)

What would keep you from taking Tamoxifen to prevent breast cancer?

8____ DON'T KNOW
9____ REFUSED

30. Do you currently smoke cigarettes?

1___Yes
5___No
8____ DON'T KNOW
9____ REFUSED

Closing

Those are all the questions I have for now. Thank you so much for taking the time to complete this interview. I would now like to take a moment to schedule a time for you to come into our office for your face-to-face interview. But, first let me verify your contact information.

*****_Go to Caller Information Sheet_

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Step 4: **Follow-up survey**: As exploratory outcomes, women will be mailed a one-page survey one-month after their visit to see if they talked to their gynecologist or any other physician about Tamoxifen, and if so, what was discussed. We will also ask questions to assess their perceived BC risk and overall weighing of Tamoxifen's risks and benefits to see if the lab results are sustained **(see One-Month Follow-up Survey).**

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